

Annual Report 10.11



BETTER HEALTH THROUGH RESPONSIBLE SELF CARE





What is Self Care?



SELF CARE – EMPOWERING CONSUMERS FOR A HEALTHY AUSTRALIA

THE INTEREST IN SELF CARE

Across the community, there is greater awareness of the many things people can do to maintain good health and wellbeing. Self care embodies the notion of people taking greater personal responsibility for their health through nutrition, exercise and appropriate use of self-medication to treat and prevent illness.

WHY SELF CARE IS IMPORTANT

Good health is a precious commodity. Many more people are aware that keeping well and staying well is key to a productive and longer life. There has been a range of major Government reports outlining the benefits to individuals, communities and the nation from improved personal health. The increasing cost of healthcare is also exerting considerable strain on public health budgets. It is forcing everyone to examine what can be done to help prevent disease, manage existing conditions and improve the quality of life and general health of the population.

ASMI AND SELF CARE

ASMI believes that self care brings the real prospect of improved health outcomes across the entire community. It is something that needs broad involvement - consumers, healthcare professionals, government and industry, working together. With the encouragement of professionals, and supported by education and public awareness campaigns, ASMI believes Australians can be handed the knowledge and tools to assume greater responsibility for their health and help build a healthier country.

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PRESIDENT'S MESSAGE



As a rule, Associations are perpetually busy – by their very nature, they tend to be staffed by small, enthusiastic groups of talented individuals who manage to make tight deadlines and limited budgets work extraordinarily well. ASMI is no exception.

In addition to the usual day-to-day activities and ongoing projects, this year the Secretariat also undertook a number of major reviews of key activities such as our annual conference and AGM, Sales & Marketing Awards, face-to-face and online induction programs, members dinner events and our database system.

Via a member survey early in the year, we asked members to tell us what they believed were the burning issues and to rate the current effectiveness of the Association in meeting their needs.

Not surprisingly, challenging the increasingly risk-averse regulatory environment is still seen as a top priority. To this end, ASMI continues to work with the Therapeutic Goods Administration (TGA) to address industry's concerns and to determine ways to resolve them to the benefit of not only our industry, but also the government, consumers and other key stakeholders in health.

ASMI is looking forward to working with the TGA on its recently announced Business Process Reforms for OTC Medicines. This project offers a great opportunity to improve efficiency and predictability in the way the TGA handles variations and new product applications. The project will

be conducted by two teams: a CEO Forum to provide strategic direction and a Working Group to develop the reform details. Throughout this project we will be advocating for certainty of data requirements, predictability of evaluation times, efficient processing of applications and the maintenance of a risk benefit approach that is appropriate for OTC medicines. While we are supportive of a transparent regulatory process, we will maintain our commitment to protecting the intellectual property of OTC sponsors.

Self care is, and will continue to be, a strategic focus of ASMI. We've made major headway in recent years through building and maintaining key stakeholder relationships, particularly in the pharmacy area. Within the broad concept of self care, our focus is on the key areas of access to medicines, scheduling, health literacy and the treatment of minor ailments by pharmacists.

But despite focusing on self care for quite some time, we understand that the term is still a nebulous one for many people, including our own members. So our aim over the coming 12 months, as we round out the final year of our three-year Strategic Plan, is to simplify the messages and increase our communication of them to all the key players.

On the wider healthcare front it has been an uninspiring year in many respects, mainly due to a slowing of many of the Government's promised health reforms. One bright note was the formation of the Australian National Preventive Health Agency (ANPHA) and, more recently, its Advisory Council chaired by Dr Christine Bennett. This signifies a renewed effort by the Government to implement health reform with a greater focus on preventative health and personal responsibility for health. ASMI intends to build a good relationship with this body to further promote the role of non-prescription medicines in preventative health and wellbeing.

I commend the ASMI Secretariat team for another year of hard work. Fittingly, their efforts were strongly acknowledged by our members in the recent survey. Under Deon Schoombie's guidance, I believe the Association has many new and exciting avenues to explore, both for members directly and for the industry as a whole.

I'd also like to acknowledge my predecessor, Ralf Dahmen, who was President of ASMI for seven years. Ralf continues to serve on the Committee of Management and we appreciate the benefit of his counsel.

I thank our members for their ongoing support and for their input, feedback and guidance, which is invaluable as the Association strives to do what needs to be done. I have enjoyed the additional challenges that have come with the role of President of the Association. Of all the current challenges facing our industry, getting the OTC Medicines Business Process Reform project underway is the major development.

ASMI is now well positioned to take our members' stories to the wider world and achieve results that will ensure the continued success and viability of our industry.

A handwritten signature in black ink, appearing to read 'Lindsay Forrest'. The signature is stylized and fluid.

Lindsay Forrest
ASMI President

ASMI COMMITTEES AND TEAMS

COMMITTEE OF MANAGEMENT

From top left to right:

Leanne Blair, MSD Consumer Care (from July 2011)
 Ralf Dahmen, Omega Pharma
 Luke Fitzgerald, sanofi-aventis Australia (from August 2011)
 Lindsay Forrest, Reckitt Benckiser
 Trevor Juniper, Quintet Pharmaceuticals
 Chris Gamblin, MSD Consumer Care (to July 2011) *not pictured*
 Phil Lynch, Johnson & Johnson Pacific

From below left to right:

Trevor Norman, Combe Asia-Pacific
 Andrew Phillips, Novartis Consumer Health
 Graham Read, GlaxoSmithKline Consumer Healthcare (to July 2011)
 Paul Rose, Pfizer Australia Consumer Care
 Mark Sargent, Bayer Healthcare Consumer Care
 Jayne Senior, Mentholatum Australasia (to April 2011)



EXECUTIVE SUBCOMMITTEE



SUBCOMMITTEES, WORKING GROUPS, PANELS AND TEAMS

ASMI COMPLAINTS PANEL

(Chair: Alan Limbury, Strategic Resolution)

MARKETING AND ETHICS SUBCOMMITTEE

(Chair: Jayne Senior, Mentholatum Australasia (to Aug 10); Filomena Maiese, formerly Johnson & Johnson Pacific Pty Ltd, now ASMI)

MEMBERSHIP SERVICES SUBCOMMITTEE

(Chair: Vacant)

PROMOTIONAL MONITORING PANEL

(Chair: Dr Michael Wyer, Consultant)

SELF CARE SUBCOMMITTEE

(Chair: Mark Sargent, Bayer Healthcare Consumer Care)

REGULATORY POLICY SUBCOMMITTEE

(Chair: Lynda McFarlane, Bayer Australia Ltd)

Complementary Medicines Working Group

(Chair: Michael Gepp, Pathway International)

Manufacturing Working Group

(Chair: Michael Gepp, Pathway International)

OTC Working Group

(Chair: Peter Thanopoulos, GlaxoSmithKline Consumer Healthcare)

Scheduling Working Group

(Chair: Vacant)

Sunscreen Team

(Chair: Kerry Greive, Ego Pharmaceuticals)

ABOUT ASMI

ASMI: REPRESENTING THE AUSTRALIAN CONSUMER HEALTHCARE INDUSTRY

ASMI is the peak body representing companies involved in the manufacture and distribution of non-prescription consumer healthcare products in Australia. ASMI also represents related businesses including advertising, public relations, legal, statistical and regulatory consultancy companies and individuals.

Our purpose is to represent the best interests of our Members through negotiation, debate and co-operation with a wide range of stakeholders in our own region and around the world. We also gather the best current information and intelligence from diverse sources and disseminate it to our Members to alert them to potential issues that may affect their products and their markets.

ASMI is a member of the World Self-Medication Industry (WSMI) and our President, Lindsay Forrest, and Executive Director, Deon Schoombie, sit on the Board of that organisation. WSMI is a non-government organisation (NGO) made up of over 50 member associations located on all continents of the world and with affiliation to the World Health Organization (WHO). Our membership of WSMI enables us to track and contribute to international trends and developments in consumer healthcare.

ASMI VISION

Better health through responsible Self Care

ASMI MISSION

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

ASMI VALUES

- Drivers of change through Member contribution and industry interaction.
- Best practice in governance and service.
- Committed to representation by consumers, relevant industry sectors and healthcare professionals.
- Consistent in policy and action.
- A learning organisation committed to competency development.

ASMI STRATEGIC PLAN 2009-2012

STRATEGIC OBJECTIVE 1:

ASMI Self Care agenda is formally included in National Health Care Policy

STRATEGIC OBJECTIVE 2:

Facilitate a regulatory environment based on risk benefit, one which is not risk averse and which creates a level playing field

STRATEGIC OBJECTIVE 3:

Be the Voice for the whole Consumer Healthcare Products Industry



MAIN ACHIEVEMENTS OF THE PAST YEAR

Our resources were invested in pursuing ASMI's Strategic Objectives and addressing critical issues which could have an impact on our industry

The two main areas of strategic focus were progressing our self care agenda and pursuing a favourable regulatory environment.

More information on ASMI's Strategic Plan is available on the ASMI website: www.asmi.com.au

SELF CARE

The strategic review in April 2011 determined key priorities for the Self Care Subcommittee. The first was communicating ASMI's self care agenda and messages with greater clarity and consistency. A key insight from the member survey, which was conducted in early 2011, was the need to simplify ASMI's self care key messages.

ASMI members and key stakeholders were consulted in the process of simplifying messages to ensure alignment and clarity, and a new communications framework to convey the re-crafted messages was developed. The new self care messages were launched at ASMI's 2011 annual conference and will be integrated into all future member and stakeholder engagement activities.

The second key area is the development of a business model for the management of minor ailments by pharmacists. ASMI is working with the Pharmaceutical Society of Australia (PSA) and other stakeholders on this project and the aim is to run a pilot to test and refine a model for wider adoption by community pharmacists.

ASMI continues to foster alliances and partnerships to drive the self care agenda. NPS and ASMI commenced work on a project aimed at supporting informed consumer decision making and QUM in self-selection environments.

NEW SCHEDULING FRAMEWORK

The new scheduling framework came into effect in July 2010. ASMI assisted members with the transition to the new scheme and we also made several submissions on behalf of industry. Despite a number of disappointing scheduling and Appendix H decisions, ASMI was encouraged to see some successful applications.

REVIEW OF ARGOM

The major review of the Australian Regulatory Guidelines for OTC Medicines (ARGOM), which commenced in early 2009, is yet to be completed. All draft chapters were completed at the end of February 2011. ASMI continues to advocate for the draft document to be released for public consultation without further delay.

The overall objectives of the review are to ensure that the guidelines are consistent with the principles of minimum effective regulation and that they reflect current TGA business practices applicable to OTC medicines. In the main, ASMI is satisfied with the proposed revisions. The new guidelines will provide greater clarity for sponsors, especially for more complex applications. This should ensure complete applications which will translate into greater predictability in terms of evaluation timeframes.

PAEDIATRIC COUGH AND COLD MEDICINES

Following the 2008 TGA review of substances used in paediatric cough and cold medicines, the Advisory Committee on Medicines Scheduling (ACMS) recommended in 2010 that 15 active ingredients be rescheduled when used in children in various



age groups. Subsequently, the TGA proposed that an additional 5 substances be up-scheduled. This would have had a major impact on existing adult use.

Since the start of this review ASMI has worked tirelessly to put forward sensible and balanced solutions that would meet agreed objectives of safe use in children. ASMI consistently maintained its position on various aspects, i.e. the long history of safe use in Australia, lack of evidence of misuse or abuse in the Australian market, favourable adverse event data in this age group, and current regulatory controls.

ASMI welcomed the decision in August 2011 not to change the scheduling of all the active ingredients under consideration, but instead implement age-based restrictions via alternative regulatory mechanisms. This was a significant win for industry.

ASMI will continue to work with the TGA to ensure that the regulatory changes are appropriate and that implementation timelines are adequate to ensure a smooth transition to the new arrangements.

COMPLEMENTARY MEDICINES

ASMI continued to lobby for the implementation of measures to strengthen the regulation of complementary medicines. This included a review of the registration pathway for complementary medicines and the evaluation of new substances. ASMI was a member of a working group which prepared a range of recommendations for reform to the Parliamentary Secretary for Health and Ageing.



ASMI worked closely with the Office of Complementary Medicine (OCM) to develop workable solutions for issues related to the TGO 78 and its adoption of the default pharmacopoeial standards. The proposals will be considered by the Therapeutic Goods Committee.

Through our participation in the Office of Complementary Medicines/Industry Consultation Group (OICG), a greatly expanded list of coded indications was developed to assist sponsors with the selection of permissible claims and indications for listable medicines at the time of electronic lodgement. Implementation has been delayed pending the outcomes from the reviews into advertising, promotion and other complementary medicines reforms.

Industry worked with the Australian Quarantine Inspection Service (AQIS) to address obstacles experienced by sponsors who import medicines, particularly those of natural origin. This resulted in a workshop where AQIS clarified the regulatory requirements and explained procedures to assist sponsors with compliance and avoid disruption to business.

ASMI, in collaboration with OCM, presented a paper at the ARCS spring conference on the process for designing effective listable complementary medicines. We also presented a paper at the annual conference of the Australian Acupuncture and Chinese Medicine Association (AACMA) on the importance and benefit of regular contact between all branches of the complementary medicines industry.

STRENGTHENING SELF-REGULATION

In March 2011 the Working Group on the Promotion of Therapeutic Products presented its final report to the Parliamentary Secretary for Health and Ageing.

The group - comprising industry associations, consumers and healthcare professionals - was established to develop

high level principles governing promotional activities directed to healthcare professionals. These principles are to be adopted in the various industry codes of conduct to ensure consistency and a level playing field for sponsors.

Once the recommendations have been adopted by Government amendments to the ASMI Code will be presented to ASMI members for adoption. ASMI's representation on the Working Group ensured that the final report took into account the unique requirements of the OTC sector.

TGA TRANSPARENCY REVIEW

In June 2011 the Transparency Review Panel presented its final report to the Parliamentary Secretary for Health and Ageing. The Panel made 21 recommendations aimed at improving the transparency of the TGA.

ASMI was represented on the Panel and ensured that the final report was consistent with our values and recognised the unique requirements of the OTC sector.

ASMI is looking forward to working with the TGA to implement the recommendations. Adoption of the recommendations will provide real benefits to all stakeholders, including sponsors of non-prescription products.

PHARMACOVIGILANCE

ASMI collaborated with our colleagues at the Complementary Healthcare Council (CHC) to lobby the TGA to revise the pharmacovigilance requirements for registered and listed non-prescription medicines. A common guideline is now in place for all medicines and ASMI and CHC jointly presented a seminar to assist sponsors in understanding their pharmacovigilance responsibilities.

MANUFACTURING

ASMI has been successful in instigating the development and review of a range of guidance documents. The implementation of the PIC/S Guide for GMP for Medicines 2009 remained a key focus area and industry's lobbying efforts were rewarded by the publication of technical guidance documents prepared by the Complementary Medicine Technical Working Group on Ongoing Stability and Product Quality Reviews.

The Office of Manufacturing Quality (OMQ) also agreed to prepare a technical guidance document on Release for Supply and a TGA/industry working group has commenced drafting the necessary guidance. It is targeted to be available by December 2011.

The Australian Regulatory Guidelines for Good Manufacturing Practice (GMP) Clearance for Overseas Manufacturers was updated as an action arising from an OMQ/Industry Workshop. The new edition is a more user friendly document that better reflects the process and assists sponsors to submit effective applications.

An industry Guideline on Good Supplier Practice to assist members with their vendor assurance program for starting materials sourced through local suppliers/agents is nearing completion and launch.



SUNSCREENS

ASMI continued to support the development of a new Australian and New Zealand Standard for Sunscreen Testing (AS/NZS 2604) which will reference the harmonised (ISO) test methods for *in vivo* SPF determination and *in vitro* UVA-PF determination. The ISO *in vivo* SPF method has been completed and published. The ISO *in vitro* UVA-PF has undergone public consultation and is anticipated to be finalised in December 2011.



ASMI has submitted comment to Standards Australia's public consultation on the draft of the revised AS/NZS 2604, which closed 1 August 2011. The revised standard is expected to be published early in 2012. The standard will harmonise with the European Union (EU) and the USA with a maximum SPF label claim of SPF 50+.

The application of the ISO method for *in vitro* UVA-PF will introduce more rigorous criteria for the Broad Spectrum claim on sunscreen products, proportionate to their SPF.

THERAPEUTIC GOODS/COSMETICS INTERFACE

ASMI has been represented on the Cosmetic Advisory Group to National Industrial Chemicals Notification and Assessment Scheme (NICNAS), informing the process for necessary transfer of information from the Australian Register of Therapeutic Goods (ARTG) to the Australian Inventory of Chemical Substances (AICS) and ongoing new chemical processes to finalise the Cosmetic Reforms.



The Industrial Chemicals (Notification and Assessment) Amendment (Inventory) Bill 2011 to implement the necessary amendments to facilitate this finalisation of the reform was introduced to the Parliament on 6 July 2011.

THERAPEUTIC GOODS/FOODS INTERFACE

ASMI maintained a close watch on developments in food regulation. We submitted comments to FSANZ on its Review of Sports Foods, and continue to advocate a level playing field for medicines and for foods which carry therapeutic claims. ASMI has representation on the Australian Food & Grocery Council's (AFGC) Health, Nutrition and Scientific Affairs (HNSA) Committee and maintains a close relationship with the AFGC.



QUALITY USE OF MEDICINES (QUM)

An NPS Non-Prescription Medicines Working Group has been established to work on projects to support QUM. Current areas of focus are improved OTC medicines labels, and strategies to support informed consumer decision-making and QUM in retail outlets. ASMI provided input to an NPS flyer on analgesics for consumers with back pain and provided information on inclusion of measuring devices with children's medicines.

ASMI continues to support Life Education Australia (LEA) in their programs to raise awareness of QUM amongst children. We believe this support is well aligned with our strategic objective to expand self care in the community by raising health literacy.

We maintained our involvement in the Consumer Medicine Information (CMI) Quality Assurance Reference Group (QARG), the Electronic Distribution Working Group for CMIs and the ARCS Regulatory Education Subcommittee.

CREATING A GLOBAL RISK BENEFIT FRAMEWORK FOR OTC MEDICINES

The World Self-Medication Industry (WSMI) is working on a new approach to evaluating the risks and benefits of non-prescription medicines.

ASMI's Executive Director, Deon Schoombie, is a member of the WSMI Taskforce on OTC Modernization, which is chaired by Cavan Redmond, Worldwide President for Animal Health, Consumer Healthcare and Corporate Strategy at Pfizer Inc.

Underpinning the creation of the Taskforce is the fact that over-the-counter (OTC) medicines offer tremendous socioeconomic benefits to society, yet they are not viewed in a holistic way. Risk considerations are weighted heavily while the benefits of products are often given little or no consideration at all.

Globally a number of regulatory challenges threaten the future of the industry and could lead to restrictions on consumers' access to non-prescription medicines.

Stricter standards of documentation are being requested for OTCs with manufacturers increasingly being asked to update dossiers to prescription medicine standards for products that have been used safely and effectively for years. The Taskforce believes that any review of established ingredients should establish meaningful improvement to the existing efficacy and safety data.

Risk aversion by regulators is a growing trend which conflicts with pressure on manufacturers to innovate and bring new products to market. By definition, innovation requires some degree of risk and appropriate evaluation of the benefits of the risk, rather than aversion to it, is necessary to foster it.

The use of prescription product standards to measure non-prescription products is inappropriate, given that OTCs do not carry the same level of risk as many medicines available by prescription only. New ways to measure the specific benefits and risks of OTCs, as well as their safety and efficacy, need to be found.

Public concern and political attention to OTC issues are often due to them being taken out of context by the media. This, in turn, can lead to regulatory change that, arguably, does not necessarily result in enhanced public health and safety.

Reports of product misuse are troubling but limiting access to these products is not always the best way to deal with the problem of abuse and it effectively punishes those consumers who are using the products as intended.

Currently, around the world, key regulatory bodies, including our own Therapeutic Goods Administration (TGA), are undertaking reviews of their processes including their approach to risk management. The Taskforce believes that industry must be part of this dialogue in order to ensure that resulting regulatory solutions offer a balanced approach to risk/benefit.

Under the guidance of the Taskforce three risk analysis experts – Professor Eric Brass from UCLA in the US; Professor Ragnar Lofstedt from King's College London; and Professor Ortwin Renn from the University of Stuttgart in Germany - are developing a model which will be published in a prestigious peer-reviewed journal.

The aim is to develop a practical decision-making tool to evaluate the specific benefits and risks associated with OTCs and to help guide regulators' decisions.

A consistent and standardised framework will help to encourage greater transparency and understanding which could lead to better collaboration between industry and regulators. Ultimately, this would have a direct impact on consumer confidence, public health (both outcomes and consumer satisfaction) and industry vitality and innovation.



THE RESURRECTION OF ANZTPA

In June 2011 the Australian and New Zealand Prime Ministers announced plans to revive the creation of a joint therapeutic goods regulator – the Australia New Zealand Therapeutic Products Agency or ANZTPA.

The benefits of a joint scheme are obvious: a single harmonised framework will improve efficiencies in regulation and reduce regulatory costs for industry. It will also increase accessibility for consumers.

The new plan will be completed via a three-stage process over the next five years, the first stage of which began in July 2011 with information and resource sharing between the countries' existing regulation agencies - the Therapeutic Goods Administration (TGA) in Australia and Medsafe in New Zealand.

Stage two will see the establishment of a single entry point for industry and agreement on the future joint framework, although the existing regulators will continue to make their own regulatory decisions. During these two stages, a reduction in red tape is expected due to only one set of requirements needed to operate in both countries.

As integration becomes more concrete, stage three will see the joint agency formally established, following a review of progress in stages one and two.

The concept of a joint regulatory framework for all therapeutic goods was first agreed between the two nations back in 2003. But after four years of extremely resource-intensive work and consultations by both governments, the pharmaceutical industry and key stakeholders, negotiations were abandoned in 2007 after NZ failed to pass enabling legislation.

This was a disappointing outcome for the many people and organisations involved in the process so there is a degree of cautious optimism in the resurrection of the project. The key question it poses, however, is: what will be different this time?

The 2003 Treaty remains in place, despite the original ANZTPA's collapse. While this Treaty covers regulation of all therapeutic goods, during the first stages of this new process, the NZ government will introduce a stand-alone scheme for domestic regulation of natural health products that it terms 'low risk complementary medicines'. This separate framework will be reviewed in five years' time and NZ natural health product manufacturers will be afforded an opportunity to decide whether or not to be integrated into ANZTPA regulation.

The other main difference this time around is that implementation will take place in stages, instead of developing the entire package upfront before the doors of the new agency open.

Overall, the renewed push to join the two regulators has merit and would seem to build on the TGA Transparency Review.

For our industry here in Australia, and in particular for our members, the wins are likely to be: a single market with one set of regulatory regulations and reduced costs.

It is an opportunity to implement best practice regulation and will advocate a "best of both agencies" approach.

ASMI is looking forward to participating in further consultations and discussions as the process gains momentum over the coming weeks and months.



EXECUTIVE DIRECTOR'S MESSAGE



My first 12 months in the Executive Director's chair have been full of activity, externally through regular engagement with ASMI's key stakeholders and internally through meeting with members and activities within the secretariat.

Soon after taking on the new role I embarked on a program of member visits to get members' views on "the ASMI experience". It soon became clear to me that a comprehensive survey was required to gain a full understanding of member needs and expectations and to identify the gaps. The survey results provided clear indications of what needs to be done and efforts are underway to respond accordingly.

We conducted a review of all governance arrangements with a view to implementing industry best practice. With guidance from industry experts, and the support of our President and the Committee of Management, we've commenced implementation of strengthened policy and governance structures. All these activities are aimed at maintaining the highest standards in the management of the association and accountability to ASMI members.

In January 2011 the Therapeutic Goods Administration (TGA) contract to provide administrative services to the Therapeutic Goods Advertising Code Council and the Complaints Resolution Panel was awarded to ASMI. We immediately commenced a review of business processes and, in collaboration with the TGA, implemented streamlined processes to address chronic back logs and ensure timely processing of complaints. The back logs have been addressed, new complaints are processed

as they are lodged and discussions are underway with the TGA for increased funding to maintain this pace.

Labelling continued to be hotly debated and ASMI participated in several workshops and discussion groups. We made submissions to the Australian Council on Safety and Quality in Healthcare (ACSQH) and the Consumers Health Forum (CHF) and also participated in the CHF Medicines Packaging and Labelling Workshop, the ACSQH National Roundtable and the ARCS Scientific Congress.

The approach to addressing labelling issues has, to date, been fragmented and often confusing. We therefore welcome the TGA review of all medicines labels to ensure a coordinated and consistent approach to any reforms. ASMI has, for many years, been at the forefront of label innovation and we need to maintain that leadership position and be responsive to consumer needs and community expectations.

ASMI was a member of the Promotional Working Group which developed proposals to strengthen and standardise self-regulatory controls governing promotional activities directed at healthcare professionals. The working group agreed a series of key principles to be incorporated in the various industry codes of practice with a view to creating consistency and a level playing field between industry sectors. Once the recommendations have been endorsed by Government, proposals for amendments to the ASMI Code of Practice will be presented for consideration and endorsement by the membership.

The regulatory framework for complementary medicines continued to attract scrutiny and public debate – regrettably, mostly negative and damaging. ASMI has been a strong advocate of reforms that would strengthen the regulatory framework for complementary medicines, to protect the reputation of industry and to maintain public confidence in complementary medicines. We were pleased to be part

of a working group which made recommendations to the Parliamentary Secretary. The group put forward a range of proposals to strengthen the framework to maintain public confidence in the regulation of complementary medicines. While we agree with most of the recommendations we remain concerned about a proposal to mandate a label disclaimer to indicate that listable products are not subject to pre-market assessment of efficacy. We will continue to pursue an evidence-based approach to any regulatory intervention put forward.

We still await the Government's proposals for reform in relation to advertising controls. The focus of reforms in the advertising area are pre-approvals, complaints handling, and penalties and sanctions for non-compliance. These reforms have the capacity to change the way we do business in our sector and ASMI will continue to work closely with the TGA and other key health stakeholders to ensure the best outcomes for industry and consumers.

We were pleased to be invited by the Hon. Kim Carr MP, Minister for Innovation, Industry, Science and Research, and Health Minister, Nicola Roxon, Co-Chairs of the Pharmaceutical Industry Working Group (PIWG), to discuss current issues facing the non-prescription medicines sector at the group's November 2011 meeting.

In May our Committee of Management agreed to another three-year partnership between ASMI and Life Education Australia (LEA). The funding will go towards helping LEA to build its research and evaluation capacity. Previously, our partnership with LEA enabled the delivery of the Medicine Matters program to over 300,000 school students, aged 8-11. We look forward to enhancing the partnership and investing in increasing awareness of Quality Use of Medicines (QUM) amongst younger Australians as part of our strategic objective to expand self care by raising health literacy.

ASMI SECRETARIAT

This year also saw the announcement of plans to resurrect the Australia & New Zealand Therapeutic Products Agency (ANZTPA). It is our hope that the efforts made by all parties during the previous attempt to create a joint agency will set the direction for timely consultation processes and implementation timelines to ensure minimum disruption during the transition to the new agency.

Within the ASMI Secretariat we have achieved much this year with major reviews of our Sales & Marketing Awards program, annual conference, industry training and member induction programs. In August 2011 we welcomed a new Marketing & Business Development Director, Filomena Maiese, who has extensive experience in industry over many years. The goals for the next 12 months will be to start implementing the results of major program reviews, engage with our members to find out how we are servicing their needs, and develop exciting events and activities to further increase the value of membership.

On the global front, ASMI was part of a WSMI Taskforce on OTC Modernization which guided the development of a model for assessing the risks and benefits of non-prescription medicines. The work will be published later this year or in early 2012 and country associations are in the process of engaging with regulatory agencies to discuss the new decision-making tool.

ASMI and NZSMI will be hosting meetings with the TGA, Medsafe and industry where one of the international experts involved in the development process will present and lead discussions on the model. The primary objective of the work is to ensure an appropriate OTC regulatory culture globally and to emphasise the role of non-prescription medicines in self care and public health generally.

As a final comment: our overarching goal is to raise ASMI's profile with key stakeholders, the media and government so we can better service our members and ensure their voices are heard on the issues they face.

I look forward to the challenge and I hope you will support our team as we go about these important tasks over the coming year.



Deon Schoombie
Executive Director



From left to right,
standing:
Catherine Gwynne
Anthony O'Byrne
Ruth Kendon
Janet Zanetti
Deidre Cox
Lesley Speechley
Tracey Shenton

From left to right,
seated:
Filomena Maiese
Deon Schoombie
Steve Scarff

Inset: Mary Emanuel

Deidre Cox, Communications & Member Services Manager

Mary Emanuel, QUM Manager

Catherine Gwynne, Regulatory & Technical Manager – OTC Medicines

Ruth Kendon, Regulatory & Technical Manager – Complementary Medicines

Filomena Maiese, Marketing & Business Development Director (from Aug 2011)

Anthony O'Byrne, Advertising Services Manager

Jane Parker, Projects & External Liaison Manager* (to Aug 2011)

Steve Scarff, Regulatory & Scientific Affairs Director

Deon Schoombie, Executive Director

Tracey Shenton, Accountant

Lesley Speechley, Executive Assistant/Office Manager

Janet Zanetti, Office Administrator

* Former staff member



MEETING THE NEEDS OF OUR MEMBERS



I am quite excited about the opportunities ahead for both the industry and ASMI.

My 18 years experience in industry gives me a great appreciation of member needs and industry issues and it will assist in determining how ASMI can better support its members and seize opportunities for our industry.

ASMI recently conducted a comprehensive member survey to determine members' views on the association's strategic direction, member expectations and the degree to which these expectations are met. We would like to thank members for providing us with rich insights on the areas they feel passionate about. We would also like to thank UltraFeedback for conducting the research and distilling the findings into clear messages. The feedback we received indicated that it was a very positive experience for everybody involved.

Overall, our members have a favourable perspective of and positive experience with ASMI, benchmarking us strongly relative to other associations. The Secretariat is regarded as extremely knowledgeable, professional and helpful in assisting members with issues and providing advice and support.

Several opportunity areas emerged from this survey. The first is members' desire for ASMI to improve its outbound communications functions, both reactive and proactive, and our stakeholder relations management, internally to our members and externally to our key partners. Members would like to see ASMI's profile raised and its sphere of influence on matters impacting on our industry expanded.

In response to this we have implemented a communications development work stream to create and maintain a dynamic communications framework and activation plan aligned with the ASMI strategic objectives. As a subset of the communications development project we are also in the process of streamlining ASMI's PR processes, not only to enhance our responsiveness to issues as these emerge but to also seize industry opportunities proactively.

Another opportunity area which came through in the member survey was in broadening and strengthening ASMI's stakeholder engagement and capacity to influence. We have already taken steps in this area and have recently engaged a Canberra-based consultant to provide advice and support with greater stakeholder engagement. We are also undertaking a stakeholder perception study in order to set a baseline from which to develop a comprehensive and focussed ASMI stakeholder management plan and influencing strategies.

We also heard that ASMI members expect greater awareness of and engagement with ASMI events, services and initiatives. We have commenced developing strategies to generate awareness at all staff levels within our membership of how ASMI can support them and add value. This includes providing advice, training and education, inductions, committee involvement and networking opportunities.

Once again, we thank members for their input. ASMI looks forward to continuing to evolve our strategic direction and offer to better meet our members' needs.



Filomena Maiese
ASMI Marketing & Business Development Director

BENEFITS OF ASMI MEMBERSHIP

- Strong and effective advocacy and representation on important external committees and working groups
- Expertise and advice to keep your company abreast of issues and opportunities
- Events and training to expand your company's networks, knowledge and influence
- The opportunity to contribute to decision-making and discussion on industry issues and projects through participation on Subcommittees, Working Groups or Teams
- Access to Members Only information, discounted rates for events and opportunities to network with industry colleagues and key stakeholders

We'd be happy to discuss membership with you at any time. Contact us on 02 9922 5111 or email info@asmi.com.au

Visit ASMI online at

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ASMI ANNUAL CONFERENCE

Use of next-generation online health information services, improved health literacy and increased access to medicines were the key points of discussion at the 2010 ASMI Annual Conference, held in Sydney on 18 November.

The conference, titled *Bringing Self Care to Life*, attracted over 300 delegates from the non-prescription medicines industry, academia, healthcare professional groups and government who enjoyed a line-up of outstanding Australian and international speakers.



Bob Gann, Head of Strategy & Engagement for NHS Choices addressed the increasing sophistication and take-up of online health information services in the UK, which has led to a revolution in the way patients research and address health issues that affect them and their families.

CEO of the National Health Call Centre Network, Julian Henderson, discussed the challenge of trying to emulate this system here in Australia. The Network runs a 24/7 free telephone-based nurse triage and health information service, Healthdirect Australia, which operates currently on a much smaller scale than the UK model but, with enough funding and resources, it has the potential to become a fully-fledged e-health network.



Ross McDonald, Head of Retail & Consumer Goods for Google Australia and New Zealand gave an overview of the innovative approaches to consumer health that can be built around digital technologies. A revelation was that Google's search results reveal geographic patterns which can help to identify current and emerging health conditions across the globe.



Men's health was the focus of Professor Ian Banks, President of the European Men's Health Forum, who outlined the measures being taken in the UK to address the disproportionate mortality of men with treatable conditions. Specific strategies are required to encourage men to seek diagnosis and treatment for health problems.

Dr Tony Hobbs, a key adviser to the Federal Government on preventative health and primary care, called for greater cooperation between GPs and pharmacists to find improved health outcomes and address the burden of minor ailments.



While Dr Lesley Braun of Monash University urged greater integration of complementary medicines into the mainstream health system, including better access to advice and information on these products in the pharmacy.



A key stakeholder panel, moderated by the ABC's Dr Norman Swan, focused on The Case For and Against Advertising of Non-prescription Medicines. Much of the debate centred on the Schedule 3 (Pharmacist Only) category which, although obtained without a prescription, cannot be advertised to consumers, in many cases leaving them completely unaware of a product's existence. The panelists were: Carol Bennett from Consumers Health Forum of Australia; Bill Curtis of advertising agency CJB; Natalie Gauld from Pharma Projects (NZ); Nicholas Hall of Nicholas Hall & Company (UK); and Brendan O'Loughlin from Pharmacy4U.

In a separate session, Nicholas Hall presented the latest research on prescription-to-OTC 'switches' (downscheduling) around the world, including the substantial benefits that can result for both consumers and taxpayers. His predictions of the areas most likely to see switches in the near future include flu treatments, oral contraceptives, erectile dysfunction products and chronic pain relief.

ASMI AWARDS

SALES & MARKETING AWARDS

The 2010 ASMI Sales & Marketing Awards were presented at the Conference Dinner by the Secretary of the Department of Health, Jane Halton PSM. The Awards Dinner was hosted by Nicholas Hall of Nicholas Hall & Company (UK).

These Awards acknowledge excellence in the sales and marketing of OTC/complementary healthcare products, innovation, marketing and sales best practice, and consumer focus.

The Awards Judging Panel was made up of a consumer representative, a pharmacist, a PR agency representative and a pharmacy journalist.

ASMI SERVICE AWARDS

ASMI AWARD FOR EXCELLENCE

This award is ASMI's highest honour and recognises an individual's outstanding service to the Australian Self Medication Industry. In 2010, this award was presented to retiring ASMI Executive Director, Juliet Seifert, in recognition of her numerous achievements during 21 years in the role.



ASMI DISTINGUISHED SERVICE AWARDS

These Awards honour ASMI member company representatives who have demonstrated commitment and passion in their contribution to ASMI's activities. There were three recipients in 2010:



Elizabeth Ng, Regulatory Affairs



Mike Cocks, Advertising & Communications



Peter Kissane, Quality & Technical Management

THE WINNERS WERE:



Best Launch of a Consumer Healthcare Product

Berocca Performance Twist N Go Launch Campaign

Bayer Australia



Best Advertising/Promotional Campaign (incl. Relaunch) for an Existing Consumer Healthcare Product

Voltaren Rapid 25 Relaunch

Novartis Consumer Health Australasia



Best Self Care Program

Suvacid Heartburn Relief Launch

Novartis Consumer Health Australasia



Best Sales Force Initiative – Grocery and/or Pharmacy

Bayer Pharmacy Support Program

Bayer Australia



Best PR Initiative

Bisolvon Chesty "I hate people coughing on my head" Campaign

Palin Communications/Boehringer Ingelheim

OUTCOMES OF PROMOTIONAL PANEL REVIEWS

THE AIMS OF THIS PROCESS ARE TO:

- demonstrate the effectiveness of self-regulation of advertising, encourage compliance with the ASMI Code of Practice and the Therapeutic Goods Advertising Code (TGAC) and
- improve compliance generally across the industry for all 'below-the-line' advertising.

The Promotional Monitoring Panel is independent of the ASMI Complaints Panel and does not have the power to impose sanctions for Code breaches.

The Promotional Monitoring Panel met four times between 1 July 2010 and 30 June 2011 to review 'below-the-line' advertising materials of ASMI Member companies for compliance with the TGAC and the ASMI Code of Practice.

PROMOTIONAL MATERIALS IN THE FOLLOWING THERAPEUTIC CATEGORIES WERE SELECTED FOR REVIEW:

- Cough/Cold
- Smoking cessation
- Allergy
- Any promotion across all categories offering a special price (including 2 for 1s), prize (including competitions) or gift
- Sunscreens
- Antimicrobial
- Vitamins
- Antiseptics
- Disinfectants
- Antifungal
- Dermatological
- Acne preparations
- Skincare (excluding sunscreens)

As in the past, Member companies were responsive in delivering materials to the Panel. The panel comprised of an independent Chair, a pharmacist from the Pharmaceutical Society of Australia, a consumer representative from CHOICE, the ASMI Advertising Services Managers, the ASMI Regulatory & Scientific Affairs Director and industry representatives volunteering from Member companies in non-competing categories. Thank you very much to this team for their time and commitment to making this process a success and relevant to the needs of the industry.

A total of 443 items were reviewed, of which 143 were found to contain one or more possible breaches of the ASMI Code of Practice and the TGAC. Most of the breaches were the same breach repeated by the same company within the same campaign. The overall level of non-compliance was low with the majority of sponsors having fully compliant promotional material.

THE TYPES OF NON-COMPLIANCE CONCERNS IDENTIFIED AS A PERCENTAGE OF ALL BREACHES, WERE AS FOLLOWS:

- 82% were for lack of mandatory statements or mandatory statements that were not prominently displayed ("Always read the label"; "Use only as directed"; "If symptoms persist consult your healthcare professional"; "Your pharmacist's advice is required"), in breach of TGAC clause 6.3
- 6% did not contain the indication for the product, in breach of TGAC clause 6(3)(b)
- 3% were for misleading information and exploiting the lack of knowledge of consumers, in breach of TGAC clauses 4.2(c) and 4.2(d)
- 3% included a reference to a serious condition, in breach of TGAC clauses 5.1 or 5.2
- 3% implied other products may be harmful, in breach of TGAC clause 4.5
- 3% contained unsatisfactory presentation of scientific information, in breach of TGAC clause 4(4)

Compliance with the ASMI Code of Practice was also very high. Non-compliance issues related to lack of compliance with the TGAC as listed above, which is a breach of clause 4.3.1 of the ASMI Code. Additionally, there were 3 occurrences of a breach of 5.1.6 whereby an advertisement contained a prize competition conditional on purchase.

ASMI offers training on Code compliance and advertising regulations. This can be particularly useful for new staff to ensure compliance continues to be driven in the future.

OUTCOMES OF COMPLAINTS LODGED UNDER THE ASMI CODE OF PRACTICE JULY 2010 TO JUNE 2011

COMPLAINT 1

Date of determination:	16 August 2010
Complainant:	Dr Ken Harvey
Respondent:	Aspen Pharmacare Australia Pty Ltd ("Aspen")
Product:	Nausestil
Particulars:	Advertising associated with Nausestil in the form of a "shelf wobblers"
Alleged Breaches:	Clause 5.3.3.3 of the ASMI Code

Outcomes:

The Panel noted that:

- Although there was no brand name on the shelf wobblers, it was in the style of the Nausestil promotional material given to pharmacists.
- Nausestil is an S3 (Pharmacist Only) medicine containing 5mg of prochlorperazine maleate. The approved Product Information (PI) gives only one indication: "For the treatment of nausea associated with migraine".
- Prochlorperazine maleate does not appear in Appendix H of the SUSDP. Accordingly, Nausestil may not be advertised to consumers.
- The shelf wobblers highlighted nausea due to a range of conditions that were not listed in the PI as indications for the product.

The Panel found the shelf wobblers in breach of clause 5.3.3.3 of the Code because, without naming any product, it conveyed to the consumer, through its words and get-up, that there was a new product for nausea due to tummy upset, motion sickness, hangover and other causes, as well as migraine (the only condition for which the new product was indicated).

The Panel also found the wobblers in breach of clause 5.3.3.3 for containing generic information that contravenes the principles of the TGAC.

The Panel classified this as a Minor breach.

Sanctions:

The Panel required Aspen to:

- (1) Cease the distribution and publication of the shelf wobblers in question;
- (2) Retrieve and destroy all the shelf wobblers in question.

COMPLAINT 2

Date of determination:	26 August 2010
Complainant:	GlaxoSmithKline Consumer Healthcare (GSK)
Respondent:	Reckitt Benckiser Australia Pty Limited (RB)
Product:	Nurofen for Children
Particulars:	Various claims (outlined below) in advertising promoting Nurofen for Children directed to doctors, pharmacists and pharmacy assistants
Alleged Breaches:	Clauses 3.2.4, 5.1.3 and 5.1.4 of the ASMI Code

Outcomes:

"The NEW range of Nurofen for Children"

The Panel found that use of the words "The NEW range of Nurofen for Children", by way of introduction to the product changes, was justified and accurate. This aspect of the complaint was dismissed.

"Nurofen for Children provides babies from 3 months old effective temporary relief from teething pain, which may interfere with a good night's sleep."

The Panel found that the claim was not a claim for relief from sleep disturbance. The Panel agreed that it was common knowledge that pain may interfere with a good night's sleep. There was no breach of clauses 5.1.3 or 5.1.4. This aspect of the complaint was dismissed.

"Nurofen for Children provides ... relief from teething pain It also relieves fever for up to 8 hours ... All good reasons to recommend Nurofen for children."(emphasis added)

The Panel considered the claim for relief from fever for 8 hours in children aged 3 months to 12 years to be substantiated. The advertisement encouraged pharmacists and pharmacy assistants to recommend Nurofen for Children for teething pain and for fever, which may or may not be associated with teething. Nurofen for Children had been shown to be effective for the relief of both and it was, therefore, legitimate to claim that these were good reasons to recommend the product. The advertisements did nothing to discourage due consideration as to whether the symptoms being displayed might be caused by something else. The Panel found that there was no breach of clause 5.1.3. This aspect of the complaint was dismissed. The Panel noted that clause 3.2.4 was not an operative provision capable of breach.

Nurofen for Children provides effective temporary relief from pain associated with earache. It also starts to relieve a fever from 15 minutes onwards, giving more play time and less pain time. (emphasis added)

Nurofen for Children provides effective temporary relief from a headache. It also starts to relieve a fever from 15 minutes onwards, giving more play time and less pain time. (emphasis added)

The Panel found that the claims did not imply a direct link between fast onset of fever relief (from 15 minutes) and pain relief. There was no breach of clause 5.1.3 or 5.1.4. This aspect of the complaint was dismissed.

"Nurofen for Children offers more time without fever in the first four hours than paracetamol"

The advertised claim represented that it was wholly substantiated across the 3 months-12 years age range by Hay AD, Costelloe C, Redmond NM, Montgomery AA, Fletcher M, Hollinghurst S, Peters TJ. Paracetamol plus ibuprofen for the treatment of fever in children (PITCH): randomised controlled trial. *BMJ* 2008;337 a1302 ("Hay 2008"). RB admitted that the study did not cover the age groups 3-6 months and 6-12 years. Accordingly the Panel found the claim based solely on Hay 2008 to be in breach of clause 5.1.3. This was a Moderate Breach.

Whether the Hay 2008 data were consistent with the body of clinical evidence

GSK suggested that the Hay 2008 data were not consistent with the body of clinical evidence. The Panel found that the Hay 2008 data were not inconsistent with the body of clinical evidence. There was no breach of clause 5.1.3. This aspect of the complaint was dismissed.

"...with a safety and tolerability equal to paracetamol"

The Panel saw no reason to reject the conclusions of the study which RB used to support the claim. The Panel agreed that it was not necessary to include contraindications and warnings in the advertisements and, given the well-known contraindications for ibuprofen, it did not accept that, in the absence of such warnings in the advertising, pharmacy assistants would be likely to overlook the pack warnings. Accordingly, the Panel found no breach of the Code. This aspect of the complaint was dismissed.

Sanctions:

The Panel required RB to cease publication in any media, in relation to children aged from 3 months to 12 years, of the claim *"Nurofen for Children offers more time without fever in the first four hours than paracetamol"*, and any claim to like effect, where the sole reference on which reliance is placed to support the claim is Hay 2008.

COMPLAINT 3

Date of determination:	3 September 2010
Complainant:	Johnson & Johnson Pacific Pty Limited ("JJP")
Respondent:	GlaxoSmithKline Australia Pty Limited ("GSK")
Product:	4mg Nicabate Minis lozenge
Particulars:	Advertising promoting 4mg Nicabate Minis lozenges in the form of a television commercial (TVC)
Alleged Breaches:	Clauses 5.1.3 and 5.2.2 of the ASMI Code

Outcomes:

The Panel proceeded on the basis that The Claim ("*they may be small but they dissolve in minutes to release their full dose of therapeutic nicotine three times faster than Nicabate gum*") was literally true.

The Panel found that, in the context of the TVC and the usual circumstances in which TVCs are communicated to and received by viewers, The Claim would be likely to be understood by viewers as making the representation that the Nicabate Mini lozenge relieved nicotine craving three times faster than Nicabate gum.

On the material before it, the Panel was not satisfied that this representation was true.

The Panel noted decision No.2010-02-30 of the Complaints Resolution Panel (the CRP), which was dated 28 April 2010. Decision No.2010-02-30 concerned a similar advertisement which the CRP had found to be in breach of the Therapeutic Goods Advertising Code (the TGAC).

The Panel noted that the visual elements of the present TVC were the same as those used in the advertisement considered by the CRP.

The Panel found that, despite the changes in the wording, the present TVC made substantially the same misleading representation as was found by the CRP to breach the TGAC. The only difference was that the comparison in the present TVC was with Nicabate gum, not all NRT gum.

Accordingly the Panel found the TVC to breach clause 5.1.3 of the Code.

The Panel did not regard The Claim as making a comparison with all NRT gum nor to be showing NRT or Nicabate gum to be ineffective. The complaint of breach of clause 5.2.2 of the Code was dismissed.

The Panel found the breach to have no safety implications but that it would impact on the perceptions of consumers regarding the product and the competitor product Nicabate gum (noting that although Nicabate gum was not a product of a competitor, it was still a “competitor product” to the lozenge). This would normally have been a Moderate Breach, however the Panel noted that the definition of the ASMI Code includes the TGAC. Since the Panel found the TVC to have made substantially the same misrepresentation as was considered by the CRP, then the present breach of the Code was the same or similar to the breach found by the CRP. Accordingly, the Panel found the present breach to be a Repeat Breach of the Code.

Sanctions:

The Panel required GSK to:

- (1) Cease publication in any media, until it can be supported by clinical evidence, of any representation, express or implied, to the effect that Nicabate Mini lozenges relieve nicotine craving three times faster than Nicabate gum;
- (2) Cease publication in any media, of any representation, express or implied, relating to speed of nicotine release from Nicabate Mini lozenges unless that representation is suitably qualified by an equally prominent statement which makes it clear that the representation relating to the speed of nicotine release does not relate to the speed of craving relief; and
- (3) Pay a fine of \$50,000.

COMPLAINT 4

Date of determination:	5 May 2011
Complainant:	Nycomed Pty Ltd (“Nycomed”)
Respondent:	Johnson & Johnson Pacific Pty Limited (“JJJ”)
Product:	Pariet 10 (rabeprazole, 10mg per tablet)
Particulars:	Various claims (outlined below) in advertising promoting Pariet 10 directed to pharmacists
Alleged Breaches:	Clause 5.1.3 of the ASMI Code

Outcomes:

The Claims

“Pariet 10 is the fastest-working OTC PPI”

“the fastest-acting OTC PPI”

“Of the PPI drug class, rabeprazole (Pariet) is the fastest acting, according to early pharmacology studies and a recent safety and efficacy review of PPIs. Its high pKa of ~ 5 means it can be activated at a higher pH than other PPIs, possibly resulting in a faster onset of action”

Preliminary Issue

JJP contended that some of the material before the Panel should not be regarded as advertising or promotion by JJP because the author of the article prepared it using materials and information supplied by JJP at the publisher’s request, and thus prepared the article outside JJP’s control (since JJP did not review or approve the final content). With respect to these arguments, the Panel noted that JJP did not contend that the information it provided to the publishers differed from what was published (save that the references were omitted from one article). The Panel therefore proceeded on the basis that (save for the just mentioned exception) the articles correctly recorded the information provided by JJP. Since the information was provided in each case for publication, the Panel regarded them as advertisements for which JJP was responsible under the Code.

Footnotes and References

The Panel did not accept JJP’s contention that pharmacists would investigate the footnotes and references, read the statements and thereby understand that the “fastest-working” claim referred to conversion into active. The Panel formed the view that pharmacists would expect the references to support the “fastest onset of action” representation, not qualify or contradict it, and in this they would have been misled.

Determination

The Panel determined that the advertisements would be likely to be understood by pharmacists as making a therapeutic claim of fastest onset of action. None of the cited references supported this claim and accordingly the advertisements were in breach of clause 5.1.3.

The Panel found the breach to have no safety implications but that it would impact on the perceptions of pharmacists regarding the Pariet 10 product and competing OTC PPIs. Accordingly, this was a Moderate Breach of the Code.

Sanctions:

The Panel required JJP to:

- (1) Cease publication in any media, until it can be supported by clinical evidence, of any representation, express or implied, to the effect that:
 - (i) Pariet 10 is the fastest-working OTC PPI;
 - (ii) Pariet 10 is the fastest acting OTC PPI;
 - (iii) Pariet 10 has the fastest onset of action of any OTC PPI;
- (2) Publish a retraction statement; and
- (3) Pay a fine of \$20,000.

COMPLAINT 5

Date of determination:	5 May 2011
Complainant:	Johnson & Johnson Pacific Pty Limited ("JJP")
Respondent:	Nycomed Pty Ltd ("Nycomed")
Product:	Somac (pantoprazole, 20mg per tablet)
Particulars:	Advertising promoting Somac in the form of empty packs on display in front of counter in pharmacy
Alleged Breaches:	Clauses 5.3.2.2 and 5.3.3.1 of the ASMI Code

Outcomes:

Background

The Panel noted that Somac is an S3 (Pharmacist Only) medicine containing pantoprazole, a substance that does not appear in Appendix H of the SUSDP. Accordingly, Somac may not be advertised to consumers.

The Panel also noted that empty Somac packs had been provided to pharmacies prior to 2009 but that at some time prior to March 2009, supply of empty packs had ceased. Clause 5.3.2.2 of the ASMI Code currently provides:

"For those Pharmacist Only Medicines (Schedule 3 substances) not permitted to be brand advertised to the general public, advertisements should be directed to healthcare professionals only and must not be directed to pharmacy assistants or other non-qualified personnel."

In 2009, clause 5.3.2.2 was numbered 5.4.2.2 and, prior to July 2009, the explanatory note in relation to that clause provided:

"Except for those Pharmacist Only Medicines (Schedule 3 substances) for which direct to consumer advertising is permitted, promotional or advertising material relating to Pharmacist Only Medicines (Schedule 3) must not be visible to the public. Advertising and promotion of Pharmacist Only Medicines (Schedule 3) not listed in Appendix H of the SUSDP by way of empty packs does not constitute a breach of the requirements."

In July, 2009, the last sentence of the explanatory note was deleted following legal advice to ASMI that it was incorrect.

The Panel noted that at the time when the empty Somac packs were distributed (and there is no evidence of distribution after March 2009), the Code encouraged empty pack advertising of S3 products, even though it was unlawful.

Determination

Under the circumstances outlined above, the Panel was not disposed to find Nycomed to have breached the Code in supplying the empty Somac packs prior to the deletion of the incorrect sentence of the explanatory note, even though the more generally-worded Clause 4.2 of the Code required ASMI Members to comply with the relevant provisions of Commonwealth Acts and Regulations which pertain to the functions and operations in the industry.

Accordingly, the complaint was dismissed.

Despite this, the Panel recorded its disapproval of the way in which Nycomed failed to ensure the recovery and destruction of the empty packs in March 2009 and for two years thereafter. It was not until April 2011, after the formal complaint had been delivered and after the formal response failed to satisfy JJP, that Nycomed requested that pharmacists destroy the packs.

Sanctions:

None.

ASMI ON KEY EXTERNAL COMMITTEES*

Advisory Committee on Non-prescription Medicines (ACNM) (formerly MEC) until December 2010
Advisory Committee on Medicine Scheduling (ACMS)
ARCS Regulatory Education Subcommittee
ARCS Pharmacovigilance Education Subcommittee
ARGOM Review Project working groups
Australian Food and Grocery Council (AFGC) Health, Nutrition Scientific Affairs (HNSA) Committee
Australian Quarantine Inspection Service (AQIS) Biologicals Consultative Group
Complaints Resolution Panel (CRP)
Consumer Medicine Information (CMI) Content Quality Assurance Reference Group (QARG) (until February 2011)
CompleMED External Advisory Board
Electronic Distribution Working Group (EDWG) for CMI
Health Infrastructure Assurance Advisory Group (HIAAG)
Medicines Partnership of Australia (MPA)
National Institute of Complementary Medicines (NICM)
National Medicines Policy Partnership Forum (NMPPF)
National Roundtable on Safer Naming, Labelling & Packaging of Medicines 2011
NPS Non-Prescription Medicines Industry Group (NPMIG)
NSW Poisons Advisory Committee (NSW PAC)
National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Cosmetic Advisory Group
Office of Complementary Medicine/Industry Consultation Group (OICG)
Pharmaceutical Industry Working Group (PIWG) and PBS Reform
Pharmacy Guild QCPP Standards Committee
Pharmacy Guild R&D Advisory Panels
Precursor Industry Reference Group (PIRG)
Standards Australia Subcommittee – Sunscreen Agents Standards Development (CS042)
Standards Australia Subcommittee – Child Resistant Packaging (HE 016)
TGA Industry Consultative Committee (TICC)
TGA Internet Site Redevelopment External Reference Group
TGA Office of Manufacturing Quality (OMQ) Complementary Medicines Technical Working Group
TGA OMQ Non-sterile Medicines Technical Working Group
TGA OMQ Ad hoc Release for Supply Technical Working Group
TGA Transparency Review Panel
Therapeutic Goods Advertising Code Council (TGACC)
Therapeutic Goods Committee (TGC) and subcommittees
UNSW Board of Studies
Working Group on the Promotion of Therapeutic Goods
World Self-Medication Industry (WSMI) Board and its Subcommittees, including WSMI Taskforce on OTC Modernization



* This list includes: - participation on behalf of ASMI either by an ASMI Secretariat staff member or a representative from an ASMI Member company; or
- appointment of an ASMI Secretariat staff member or a person from an ASMI Member company as an 'expert'.

Members of ASMI 2010/2011

Honorary Life Members

Mr R Dahmen
Mr K Darke
Mr A D Glover
Dr W A Morgan
Mr D C Murphy
Dr J Pentecost
Mr D Stephens
Mr C J Tucker
Mr A J Wardell
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Allergan Australia Pty Ltd*
Aspen Pharmacare*
Baxter Laboratories*
Bayer Healthcare Consumer Care*
Biological Therapies Pty Ltd*
Boehringer Ingelheim Pty Ltd*
Church & Dwight Australia*
Combe Asia Pacific Pty Ltd*
Ego Pharmaceuticals Pty Ltd*
Ensign Laboratories Pty Ltd*
Galderma Australia*
GlaxoSmithKline Consumer Healthcare*
HealthOne Pty Ltd*
H W Woods Pty Limited*
Johnson & Johnson Pacific Pty Ltd*
Link Medical Products*
Mentholatum Australasia Pty Ltd*

MSD*
Nestle Australia Ltd*
Norgine Pty Ltd
Novartis Consumer Health Australasia Pty Ltd*
Nycomed Pty Ltd*
Omega Pharma*
Pfizer Consumer Healthcare*
Procter & Gamble Australia Pty Ltd
Reckitt Benckiser*
Ross Cosmetics Australia Pty Ltd*
sanofi-aventis Consumer Healthcare*
Smith & Nephew Pty Ltd*
Spirig Pharma Australia*
Swisse Vitamins Pty Ltd*
Tony Ferguson Licencing Trust*
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Touchstone Consulting Executive Search
UBM Medica*
Ultrafeedback Pty Ltd*
UrsaClemenger*
Ward6*
Wellvalue Healthcare Pty Ltd*
Xena Technologies Pty Ltd*

* denotes current Members (list correct at time of printing)



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SELF CARE