



2017-18

ANNUAL REPORT

Advancing consumer health through responsible Self Care



ASMI Purpose, Vision & Mission



The Australian Self Medication Industry (ASMI) is the peak body representing the majority of Australia's \$5.4 billion non-prescription medicine industry. This includes manufacturers and distributors of over-the-counter and complementary medicines.

Purpose

Promote and develop the Australian consumer healthcare products industry and to help members thrive.

Mission

To enhance the health and well-being of Australians through access to proven healthcare products.

Vision

Consumers have the information and products to practise Self Care with confidence.

ASMI's Strategic Pillars

ASMI

Influential Voice of Industry

Regulatory Environment

Supporting Self Care & Industry Viability

Self Care

Integral Part of Sustainable Healthcare System





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CEO's and Chairperson's Message



Lindsay Forrest



Deon Schoombie

ASMI has had a tremendously strong year, both in terms of the industry's policy achievements and our contribution to the evidence base for Self Care.

ASMI achieved significant reforms in the regulatory area. Under the new Scheduling Policy Framework (SPF) the default position for advertising of Schedule 3 (S3) medicines was reversed, allowing those medicines to be advertised unless there are specific reasons that it would not be in the public interest to advertise a medicine. The Federal Government also agreed to establish a multi-stakeholder working group to proactively identify suitable prescription medicines for down-scheduling. The Therapeutic Goods Administration (TGA) working group includes consumers, healthcare professionals, federal, state and territory jurisdictions, and industry, and is developing a progressive switch agenda to increase consumer access to medicines.

We strongly advocated for these policy changes and are now focused on influencing the implementation process for S3 advertising policy changes and shaping switch policy outcomes through the working group. We will also continue to pursue appropriate intellectual property protection (market exclusivity or data protection) for S4 to S3 switch applications and work closely with the TGA and members to implement the Medicines and Medical Devices Review reforms, which impact both over-the-counter (OTC) and complementary medicines.

ASMI continued to invest in research to expand the evidence base supporting Self Care and build the necessary evidence to advocate for policy reforms. The UTS Centre for Health Economic Research and Evaluation (CHERE) conducted research to underpin ASMI's push for S3 advertising reforms.

The Macquarie University Centre for the Health Economy (MUCHE) developed a research model that adds a health-economic dimension to S4 to S3 switch applications. The Victoria University Health Policy Collaboration published a landmark report, 'The Status of Self Care in Australia,' which establishes a foundation for developing specific policy proposals to embed Self Care in national health policy.

We remain vigilant in addressing threats to OTC ingredients and complementary medicines. One example of this was the recent application to up-schedule ibuprofen. ASMI successfully advocated for retention of the current scheduling since there was no evidence that would warrant any change to the current levels of access through non-pharmacy retail channels.

In October 2017, our performance on the world stage was widely applauded when Sydney hosted the World Self Medication Industry (WSMI) World Congress. Global policymakers, politicians, regulators and industry executives came together to share the latest research on the health economics of Self Care. It was the first time a WSMI conference focused solely on the value and health economics of Self Care and the research presented highlighted its growing evidence base. The social program showcased the best Sydney has to offer, and we had very positive feedback from delegates on the overall Congress experience. Guests were impressed with the calibre of the speakers and research results, and the high-quality dialogue facilitated by the presentations.

Our achievements over the past year were made possible by the unwavering support of ASMI members and the professionalism of ASMI's Secretariat. We highly value your contributions and thank you for your ongoing commitment to advancing the non-prescription medicines industry.

Lindsay Forrest
Chairperson

Deon Schoombie
Chief Executive Officer



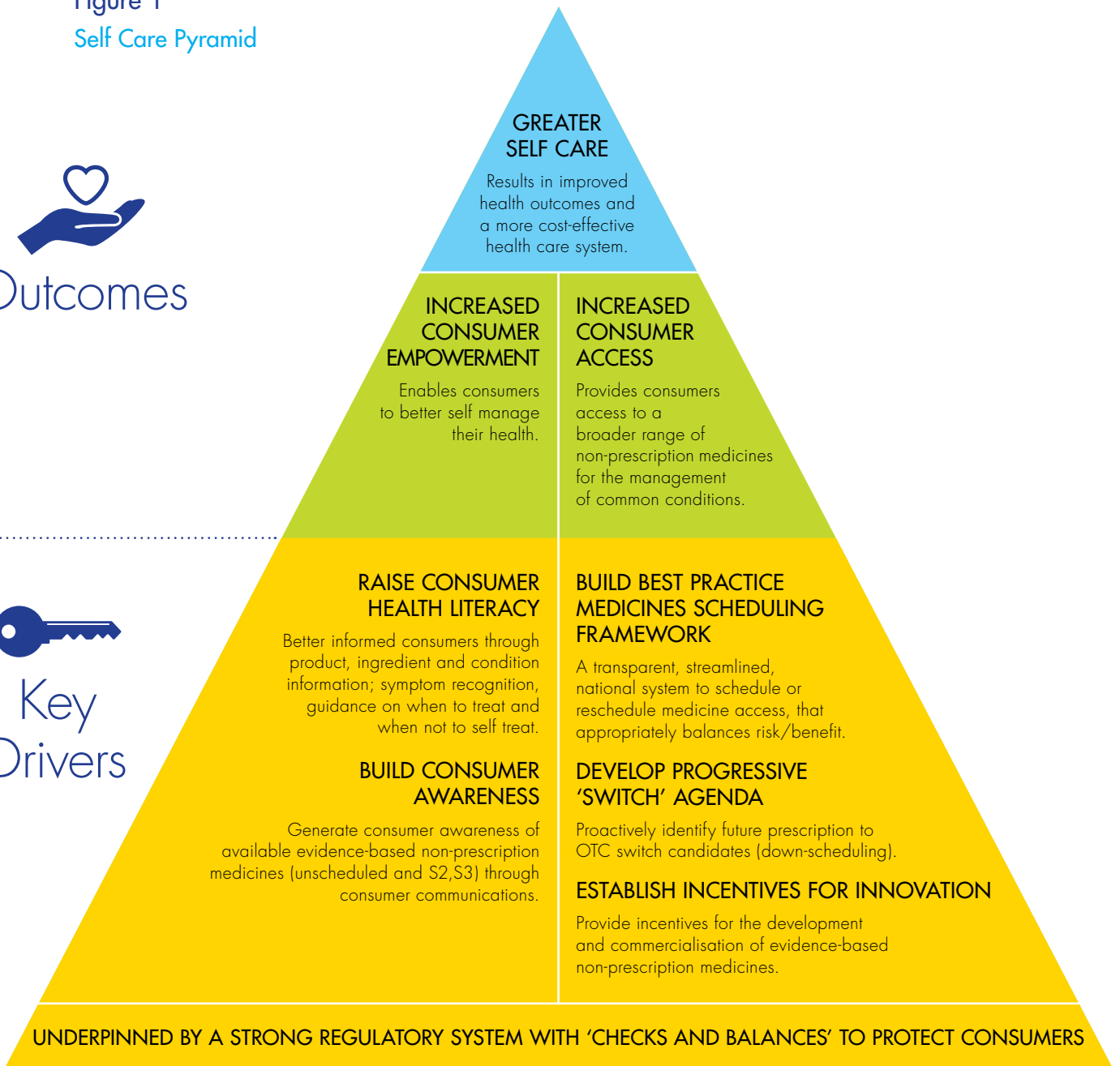


Setting the Industry Agenda

The Role of Self Care

ASMI advocates for Self Care to be elevated in national health policy. Self Care entails individuals taking greater personal interest in, and responsibility for, their health and well-being through a healthy lifestyle, responsible use of medicines, diet and exercise. Increased consumer empowerment and access to medicines are key to greater Self Care as shown in the Self Care Pyramid (Figure 1).

Figure 1
Self Care Pyramid



©ASMI (Australian Self Medication Industry)

Advocating for Increased Consumer Access to Medicines

ASMI increased its advocacy for greater consumer access to non-prescription medicines, successfully influencing policy outcomes in several areas. The key highlights are:

Scheduling policy framework

For several years ASMI advocated for the Federal Government to establish a multi-stakeholder working group to develop a Scheduling Policy Framework. The Government recently agreed to the working group and is establishing a progressive switch agenda for Australia. We are actively representing the industry through this working group.

Schedule 3 advertising

After ASMI's strong advocacy, the Federal Government agreed to change the default position to allow advertising of Schedule 3 medicines; whereas previously it was only by exception. The ASMI-commissioned University of Technology Sydney research was instrumental in driving this outcome. ASMI is now working with the TGA to implement the policy changes.

Advertising pre-approvals

ASMI believes that pre-vetting advertising is beneficial for the industry. Given the recommendation of the Medicines and Medical Devices Regulation Review (MMDR) to abolish pre-approvals in 2020, ASMI will set up a voluntary Advertising Compliance Service to replace mandatory pre-approvals and help sponsors mitigate risk. The service will start up well in advance of the abolition of mandatory pre-approval to provide confidence to sponsors, consumers and other key stakeholders.

List of permitted indications

ASMI supports the TGA's approved list of permitted indications for listed medicines, which resulted from extensive consultation with stakeholders. The key improvement is the elimination of free text and the addition of significantly more permitted indications.



VOICE OF INDUSTRY

Leading on Issues Management

ASMI is the voice of the non-prescription medicines industry. Through its media activities, ASMI promotes the industry's policy platform, protects the sector's reputation and educates consumers about the responsible use of OTC and complementary medicines to support Self Care.

ASMI issued more than 40 media statements resulting in over 150 traditional media mentions. ASMI posted hundreds of tweets as part of the discussion on key issues and throughout the WSMI World Congress reached over 60,000 Twitter users.

ASMI led media debate on key issues impacting the industry's goal to increase consumer access to medicines. The key media issues ASMI managed were:

- the efficacy and safety of OTC NSAIDs,
- paracetamol,
- complementary medicines and sunscreens, and
- the debate on the up-scheduling of OTC codeine medicines.

ASMI promoted the research launched at the WSMI Congress, including evidence that S3 advertising can improve health outcomes, research that demonstrates the economic impact of greater consumer access to medicines, and the benefits of an increased focus on preventative health.

ASMI also raised awareness of its policy successes in the media – lifting restrictions on S3 advertising, the Federal Government's decision to establish a scheduling policy framework, the two-year extension on advertising pre-approvals, and the claims included in the list of permitted indications.







Driving Regulatory Reform

ASMI continues to influence policy outcomes at a time of unprecedented regulatory reform. Our work with members, the TGA and other stakeholders drives outcomes that are practical, proportionate, effective and implemented within a realistic timeframe.

Our Policy Focus

Develop a 'switch' agenda by proactively identifying future prescription to over-the-counter (OTC) switch candidates

ASMI is representing the industry on the Federal Government's switch working group. A successful switch agenda should empower consumers, encourage industry to submit switch applications and foster innovation in OTC medicines.

Encourage switch applications by providing intellectual property protection

ASMI is advocating for improved data protection for non-prescription medicines as they do not benefit from the same level of intellectual property protection as prescription medicines. This means if a sponsor invests in additional clinical research as part of their switch application, the research outcomes will be made public and can be used by competitors, acting as a major disincentive for companies to pursue a switch application.

ASMI Advertising Compliance Service

ASMI is developing a self-regulatory 'Advertising Compliance Service' to come into effect by 1 July 2020 to replace the mandatory pre-approvals system the Federal Government is abolishing. The Marketing and Ethics Subcommittee is providing input into the model.

Therapeutic Goods Advertising Code

A new version of the Therapeutic Goods Advertising Code (TGAC 2018) comes into effect on 1 January 2019. Throughout the consultation process, ASMI advocated for a single document which was clear, objective, proportionate to risk and capable of accommodating emerging media. Many of the ASMI proposals were reflected in the final Code.

Complaints, Sanctions and Penalties

New TGA enforcement powers came into effect in 2018 following the MMDR review and accompany the new advertising Code (TGAC 2018). At the time of publication many of the details remain unclear. ASMI will continue to advocate for best-practice processes with a focus on fairness, transparency, efficiency and effectiveness.

Listed and Complementary Medicine regulatory framework reforms

ASMI is continuing to work with the TGA and members to support the smooth implementation of the major listed and complementary medicine reforms coming out of the MMDR review, including Permissible Ingredients, Permissible Indications and the Listed Assessed pathway. Changes for listed and complementary medicines have seen the introduction of activity-based costings and legislative timeframes to help improve predictability for industry. ASMI is working to see the recognition of comparable overseas regulators to support streamlined submissions. Notable progress has been made in enhancing incentives to industry for innovation with the introduction of market exclusivity for new listable substances, the listed assessed pathway, and further mechanisms under discussion to incentivise research for complementary and listed medicines.

Harmonised OTC labelling requirements between Australia and New Zealand

ASMI continues to advocate for maintaining harmonisation of labelling requirements between Australia and New Zealand. Harmonised labelling provides benefits to both markets and increases consumer access to medicines in both countries. Some of the proposed regulatory reforms (e.g. parts of TGO92) have the potential to undermine harmonisation. A harmonised approach was successfully achieved during the MMDR proposal to reformat the Product Information (PI). While the TGA commenced consultation with a unique Australian reformat they responded to industry feedback and worked with Medsafe to present a PI format consistent with the New Zealand Data Sheet format and were able to confirm its acceptance by Medsafe. This agreed format also achieved closer alignment with the European SPC.



Building the Evidence Base Supporting Self Care

ASMI commissioned research to build the evidence base for Self Care, which informed our policy platform and advocacy.



Health Economic Framework for Switch

ASMI commissioned the Macquarie University Centre for Health Economics (MUCHE) to develop a health economic evaluation framework to help inform scheduling decisions. The framework was launched at the WSMI Conference in Sydney and received positive feedback from switch experts. MUCHE's research demonstrates that an economic evaluation approach can be applied to enhance the decision-making process on how consumers access medicines.

MUCHE's framework takes account of the impact of switch on healthcare resource use and costs, and recognises that changing the schedule of a medicine can result in a wide range of health outcomes – including symptom severity and duration, incidence and progression of diseases and adverse events. Health outcomes can be aggregated to a single measure – Quality Adjusted Life Years (QALYs), which incorporates life expectancy and quality of life, and the strength of community preferences across these domains.



Complementary Medicines Evidence Forum

ASMI convened a Complementary Medicines Evidence Forum, to strengthen the evidence base for complementary medicines and contribute to more constructive, less polarised public discourse about complementary medicines.

The forum produced two papers – one is published in *Complementary Therapies in Clinical Practice* (Evidence Based Practice in Traditional & Complementary Medicine: an agenda for policy, practice, education and research) and the other has been accepted for publication in the AIMA journal: *Advances in Integrative Medicine* (Setting an agenda for strengthening the evidence-base for traditional and complementary medicines: Perspectives from an expert forum in Australia).

The Complementary Medicines Evidence Forum will use these papers to promote discussion and debate about the role of evidence in complementary medicine and contribute to a more robust and balanced dialogue.



Self Care Alliance advancing policy

ASMI spearheaded the establishment of the Self Care Alliance in 2014, which brought together stakeholders with an interest in advancing Self Care. In 2017, ASMI along with two foundation members of the alliance, HCF and Remedy Healthcare, commissioned the Australian Health Policy Collaboration (AHPC) at Victoria University to review the state of Self Care in Australia.

This landmark report entitled *The State of Self Care in Australia* acknowledged the extent to which Self Care is practised in Australia and concluded that the potential of Self Care as a component of healthy public policy is not being fully harnessed. This research will inform the future policy focus of the Self Care Alliance as it advocates for Australia to build a more sustainable health system.

Global platform driving policy

The successful 2017 WSMI General Assembly in Sydney provided a global platform to launch, share and debate the latest research on the role of Self Care with the world's thought leaders. The University of Technology Sydney S3 research and MUCHE's model of assessing the health economics of switch were warmly received by delegates, as was international research about OTC models and minor ailment schemes. We are using the research launched at WSMI to inform our evidence-based advocacy.





SELF-REGULATION

Self-regulation

ASMI has consistently supported a full range of regulatory and non-regulatory approaches to the control of therapeutic goods. In our view, the ideal set of controls includes judicious use of self-regulatory, co-regulatory and non-regulatory approaches consistent with the COAG Principles of Best Practice Regulation.

Outcomes of Promotional Monitoring Panel Reviews

The Promotional Monitoring Panel (PMP) is established in the ASMI Code of Practice. It provides a long-standing self-regulatory review process, which helps 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 (material not requiring formal pre-approval).

A full list of the promotional categories considered by the Panel is published in Section 12 of the *ASMI Code of Practice*, and includes point-of-sale material, digital media, and training materials (for both healthcare professionals and pharmacy assistants).

The Panel met twice between 1 July 2017 and 30 June 2018 to review 'below-the-line' advertising material submitted by ASMI member companies for compliance with the *TGAC* and the *ASMI Code of Practice*.

A total of 266 items were reviewed, of which 82 were found to be non-complaint with the *ASMI Code of Practice* and/or the *TGAC*. However, it should be noted that many of the breaches were repeated for the same product across different materials within a single campaign. Compliance with the *TGAC* and *ASMI Code of Practice* was generally of a good standard.

A significant proportion of non-compliance recorded related to the mandatory statements that are required when advertising therapeutic goods. The statements are required to be prominently displayed to be easily read from a reasonable viewing distance. In the material found to be non-complaint with the *TGAC* or *ASMI Code of Practice*, often these statements were inadequately displayed, sized,

or missing. Some materials had inconsistent, incorrectly placed, missing or incomplete mandatory statements.

Other areas of non-compliance were noted for use of the claim 'clinically proven', without the support of robust evidence. The use of old sales data was found in a few pieces. One item suggested endorsement by a government agency. Other non-compliance was around the use of the word 'natural'; 100% guarantee; the use of a restricted representation; and ease of access for consumers to a healthcare professional section of a website.

Complaints Panel Determinations

There was one complaint this year. The full determination is published on the ASMI website.

Children's Panadol

In October 2017, the Panel considered a complaint from Reckitt Benckiser (Australia) Pty Limited (RB) about Children's Panadol advertisements made by GlaxoSmithKline Consumer Healthcare Australia Pty Ltd (GSK).

RB complained that GSK's in-store advertising material for its "Buddy Bear" campaign for Children's Panadol appealed to minors and was directed to minors, in breach of section 5.3.4 of the ASMI Code.

The Panel considered that, taken as a whole, the advertising was directed both to parents and to children and was therefore a Minor Breach of section 5.3.4.

The Panel required GSK to discontinue the advertising and to use its best endeavours to retrieve the in-store advertising materials.





The ASMI Board

Board of Directors



Robert Barnes,
Aspen
Pharmacare
Australia
(Treasurer)



Glenn Cochran,
Reckitt Benckiser
(Australia)
(from April 2018)



Doug Cunningham,
Johnson &
Johnson Pacific
(Vice-Chair)



Lindsay Forrest,
Consultant (Chair)



Andrew Jenkin,
Pfizer Consumer
Healthcare (from
November 2017)



James Jones,
Takeda
Pharmaceuticals
Australia
(Secretary)



Stephen Moodey,
GlaxoSmithKline
Consumer
Healthcare (from
November 2017)



Alan Oppenheim,
Ego
Pharmaceuticals



Mark Sargent,
Bayer Australia



Seona Wallace,
HealthOne
(from April 2018)



Lisa Golden,
Apotex (ceased
October 2017)



Sandy Mellis,
Reckitt Benckiser
(Australia)
(ceased
November 2017)



Elizabeth Reynolds,
GlaxoSmithKline
Consumer
Healthcare
(ceased
October 2017)



Paul Rose,
Pfizer Consumer
Healthcare
(ceased
July 2017)

ASMI Board Composition

The ASMI Board composition, nomination, elections and executive roles are all governed by the ASMI Constitution.

The ASMI Board consists of up to ten Directors as follows:

- Up to six Directors elected from the Official Delegates of the ASMI Ordinary Members (Elected Directors)
- Up to four Directors appointed by the Board (Skills-based Directors).

The Elected Directors each hold office for two years and every year three of the Elected Directors retire from the Board. In advance of each annual retirement, ASMI calls for expressions of interest and holds elections for the three Director positions to be vacated. This ensures that there are opportunities for new Directors while maintaining continuity of expertise.

While each Elected Director must be the Official Delegate of an Ordinary Member, the Skills-based Directors can be drawn from a much wider set of candidates (including, for example, Honorary Life Members, Associate Members and non-members).

The ASMI Elected Directors as at 30 June 2018:

- **Robert Barnes**, Aspen Pharmacare Australia (Treasurer)
- **Andrew Jenkin**, Pfizer Consumer Healthcare
- **James Jones**, Takeda Pharmaceuticals Australia (Secretary)
- **Stephen Moodey**, GlaxoSmithKline Consumer Healthcare
- **Alan Oppenheim**, Ego Pharmaceuticals
- **Mark Sargent**, Bayer Australia

The ASMI Skills-based Directors as at 30 June 2018:

- **Doug Cunningham**, Johnson & Johnson Pacific (Vice-Chair)
- **Lindsay Forrest**, Consultant (Chair)
- **Seona Wallace**, HealthOne
- **Glenn Cochran**, Reckitt Benckiser (Australia)

Sub-committees & Working Groups

ASMI has several sub-committees and working groups that meet regularly throughout the year to work on specific projects and issues that arise.

Stakeholder Management Subcommittee

Marketing & Ethics Subcommittee

Regulatory & Technical Subcommittee

- OTC Working Group
- Complementary Medicines Working Group
- Manufacturing Working Group.

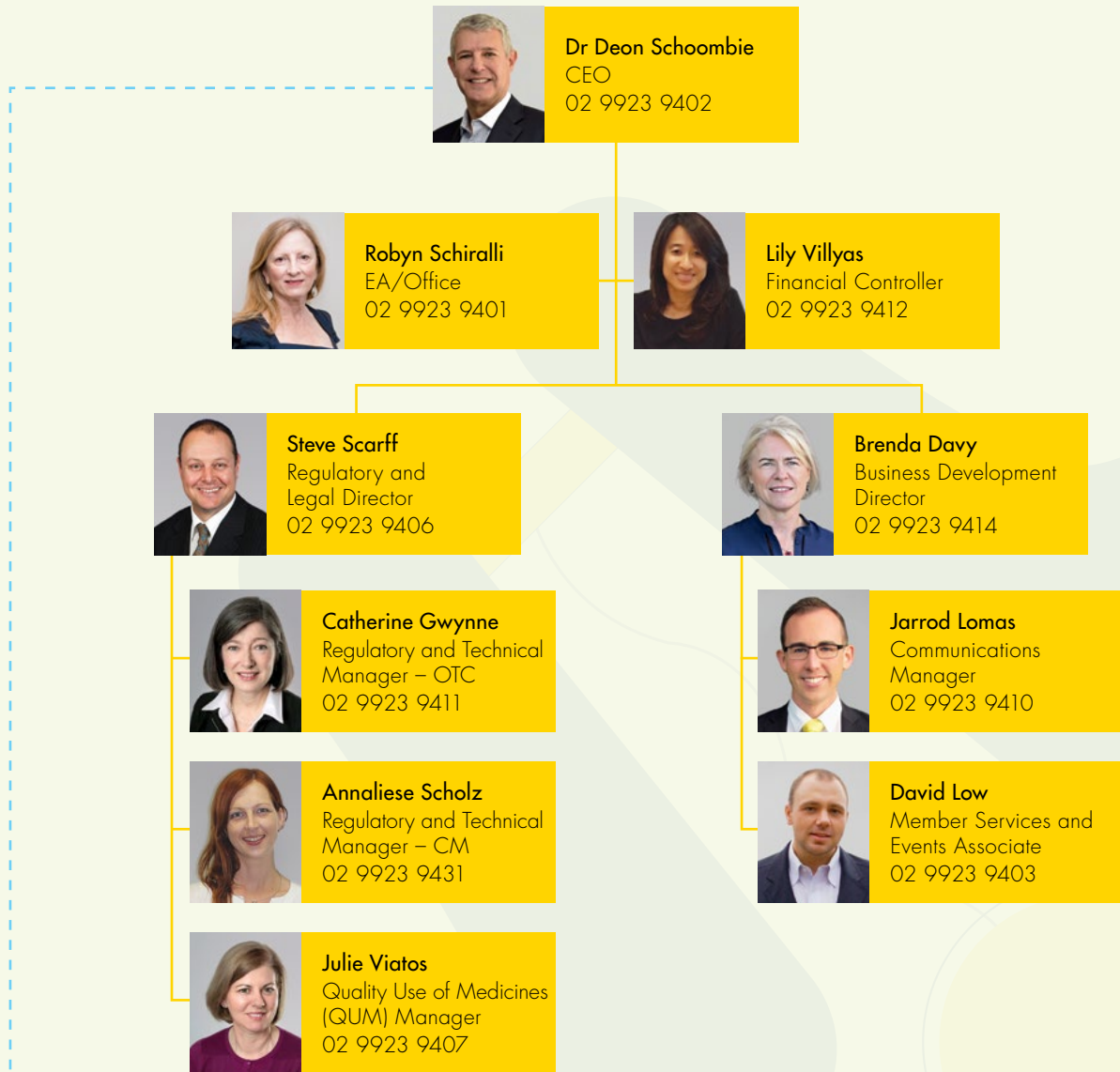




ASMI – Your Extended Support Team

ASMI Member Secretariat

Current at time of printing.



ASMI advertising services office (TGA contracts)

Josie Braid
Advertising Services
Manager
02 9923 9405

Sarah-Jane Leon
Advertising Services
Manager
02 9923 9405

ASMI – Your Extended Support Team



ASMI Member services



Advice and Support

- Pool of expertise to utilise
- Confidential advice on regulatory, technical, marketing and management issues
- Member workshops to navigate current/pending regulatory reforms



Advocacy and Representation

- “Voice of industry” on issues impacting industry, segments, ingredients
- Member conduit to media, stakeholders, government, TGA
- Strength in numbers



Shaping Industry Initiatives

- Committee, working group involvement
- Share experiences with other members
- Contribute to the ASMI position/shape industry work



Staying informed

- Keep up to date on issues
- Local and international monitoring of issues with briefs and alerts to members
- E-newsletters, alerts, events, seminars, workshops, web portal



Self Regulation

- ASMI Code
- ASMI Complaints Panel
- Promotional Monitoring Panel



Member Events

- World Class Annual Industry Conference
- Round table dinner/breakfasts
- Education Seminars
- Online Training
- Members Forums/Meet the ASMI board
- Parliamentary events
- ASMI Diamond Awards for Excellence in Marketing & Sales



Member Training

- In house training and inductions
- Therapeutic Goods Advertising Training
- Online Industry Training
- Member workshops



Australian Self Medication Industry

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Media Enquiries:

Communications Manager – ASMI

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