



# 2016-17

## ANNUAL REPORT

Advancing consumer health through responsible self care



# ASMI Vision, Mission and Strategy



## About ASMI

The Australian Self Medication Industry (ASMI) is the peak body representing sponsors of non-prescription medicines, [over-the-counter (OTC) and complementary medicines], an industry valued at more than \$5 billion in Australia and delivering \$1.2 billion in export revenue.

## ASMI Vision


Advancing consumer health through responsible self care.

## ASMI Mission

Being the voice of the consumer healthcare products industry driving a viable and reputable industry to empower more consumers with evidence-based products and information, with the aim of improving health and wellbeing.

## ASMI's Strategic Pillars


ASMI  
Strong Voice  
of Industry



Regulatory  
Environment  
Supporting  
Self Care and  
Industry Viability



Self Care  
Integral part  
of Sustainable  
Healthcare  
System





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## CEO's and Chairman's Message



Lindsay Forrest



Deon Schoombie

ASMI reinforced its position as the influential voice of the non-prescription medicines industry in 2016–17, vigorously advocating for self care to play a more prominent role in national health policy. In its advocacy, ASMI argued that increasing access to non-prescription medicines is an essential component of self care and is therefore central to creating a more sustainable healthcare system. As well as continuing to advocate for a regulatory environment that incentivises investment in innovation while protecting consumer safety, ASMI continued to build the evidence base on self care by commissioning research from reputable institutions.

The political environment for health policy was stable during the year, despite a federal election, change of Minister and Labor's call for greater health policy reform. ASMI lodged a Pre-Budget Submission in early 2017 in response to a call from the Treasurer. The submission highlights the value of the industry and non-prescription medicines to Australia's economy and provides the rationale for ASMI's advocacy to increase access to non-prescription medicines. It proposes a streamlined scheduling framework, an alternative regulatory model to create consumer awareness of Schedule 3 (S3) medicines and data protection to encourage the industry to invest in switch.

The Medicines and Medical Devices Review (MMDR) is at an advanced stage and most of ASMI's recommendations were adopted. The consultation process was constructive and ASMI strongly represented the industry's interests. The Review has reached a critical stage regarding the advertising of S3 medicines and scheduling reforms. ASMI has stepped up its advocacy for reforms in both these areas to increase consumer access to non-prescription medicines and advance self care.

In 2016, the ASMI Board commissioned Capital Hill Advisory to conduct a stakeholder audit of ASMI's impact and ability to influence the political and regulatory environment. The audit confirmed ASMI's position as the voice of the sector and its influential standing amongst stakeholders. The report made several recommendations, such as increased political advocacy to gain greater support for the industry's policy positions, which ASMI is implementing.

ASMI commissioned several studies to build the evidence base for self care and these are either completed or close to completion and will be launched at the World Self Medication Industry (WSMI) General Assembly in October 2017 which will be jointly hosted by ASMI and NZSMI. The Centre for Health Economics Research and Evaluation (CHERE) at the University of Technology Sydney completed research that found creating consumer awareness of medicines can have a positive impact on quality use of medicines. This supports the industry's proposed regulatory model for creating consumer awareness of S3 medicines. The Macquarie University Centre for the Health Economy (MUCHE) is close to completing a framework for measuring the impact of switch. This model will be launched at the WSMI General Assembly.

ASMI is preparing its 2018–21 strategic plan through a major review of operations. An external consultant will engage with ASMI members to determine their needs and expectations and examine every aspect of ASMI's operations, including its footprint in the consumer healthcare products sector.

We'd like to thank ASMI members for your continued support. We'd also like to thank the ASMI Secretariat for your commitment to advancing the non-prescription medicines industry.

**Lindsay Forrest**  
ASMI Chairperson

**Deon Schoombie**  
Chief Executive Officer



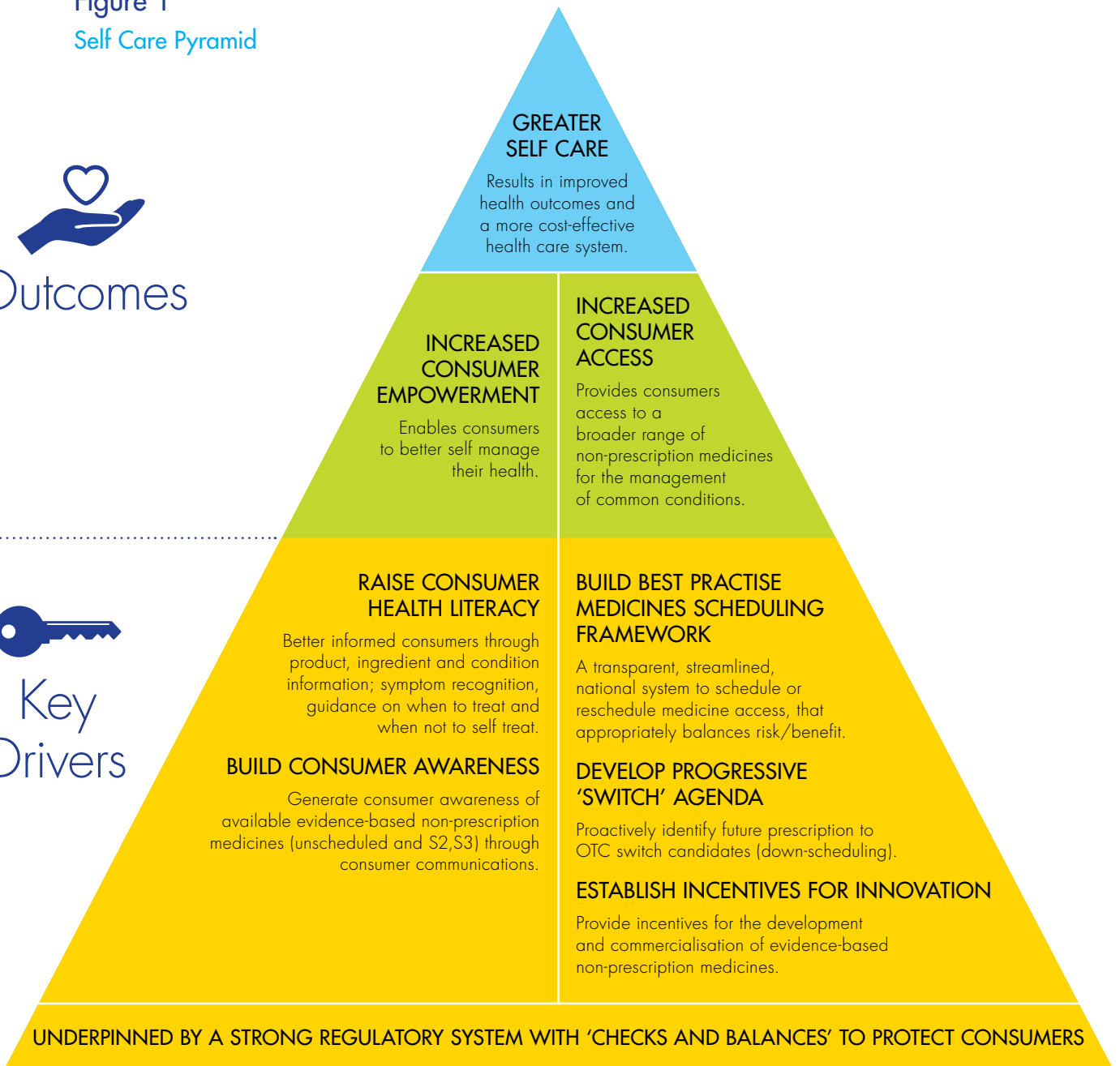


# Setting the Industry Agenda

## The Role of Self Care

ASMI advocates for responsible self care through increasing access to non-prescription medicines. Self care entails individuals taking greater personal interest in, and responsibility for, their health and wellbeing through practices including lifestyle, responsible use of medicines, diet and exercise. Increased consumer empowerment and medicines access are key to greater self care as shown in the Self Care Pyramid (Figure 1).

Figure 1  
Self Care Pyramid







# Setting the Industry Agenda

## ASMI Advocacy for Greater Access to Non-Prescription Medicines

ASMI stepped up its advocacy for greater access to non-prescription medicines to advance self care in 2016–17, participating in over 200 meetings with regulators and policymakers during the year. ASMI's advocacy is concentrated around three key policy areas – development of a 'switch' agenda and reform of the Australian scheduling policy framework; consumer advertising of S3 medicines and data/market exclusivity mechanisms to stimulate research and innovation.

## Develop a 'switch' agenda and reform the Australian scheduling policy framework (SPF)

The down-scheduling ('switch') of medicines from prescription only (S4) to S3 is a key enabler for consumers to better self manage their health, in consultation with a pharmacist. A regulatory environment favourable to switch would encourage innovation in S3 medicines and also provide significant savings to the healthcare system.

## Reduce restrictions on Schedule 3 advertising

ASMI recommends the default regulatory position be modified to become one where direct-to-consumer communications about all S3 medicines is permitted in a standardised format unless there are compelling reasons that it would not be in the public interest in relation to a specific product or product group.

## Introduce data protection/market exclusivity mechanisms to stimulate research and innovation

Mechanisms such as data and market exclusivity provide incentives for companies to invest in research and innovation for over-the-counter (OTC) and complementary medicines. Innovation is critical for the ongoing provision of high quality and accessible medicines. Data protection will encourage investment in R&D and enable greater capacity for return on that investment.

## ASMI Stakeholder Perception Audit

ASMI commissioned a Stakeholder Perception Audit in 2016 to better understand how it is perceived by key stakeholders and how it can strengthen its stakeholder engagement. The audit revealed ASMI is highly respected in political, regulatory and media circles and its policy positions are influential in shaping the policy framework for the non-prescription medicines industry. The recommendations of the report are in the process of implementation and focus on ways of further enhancing the reach of ASMI's stakeholder engagement and the impact of its advocacy.







# Leading on Issues Management

ASMI is the voice of the non-prescriptions medicines industry. Through its media activities, ASMI both protects the sector’s reputation and promotes the responsible use of OTC medicines to support self care. ASMI issued 54 media statements and prepared 19 holding statements during the last year, which resulted in 220 media mentions. ASMI posted 251 tweets and achieved 41,100 Twitter impressions throughout the year.

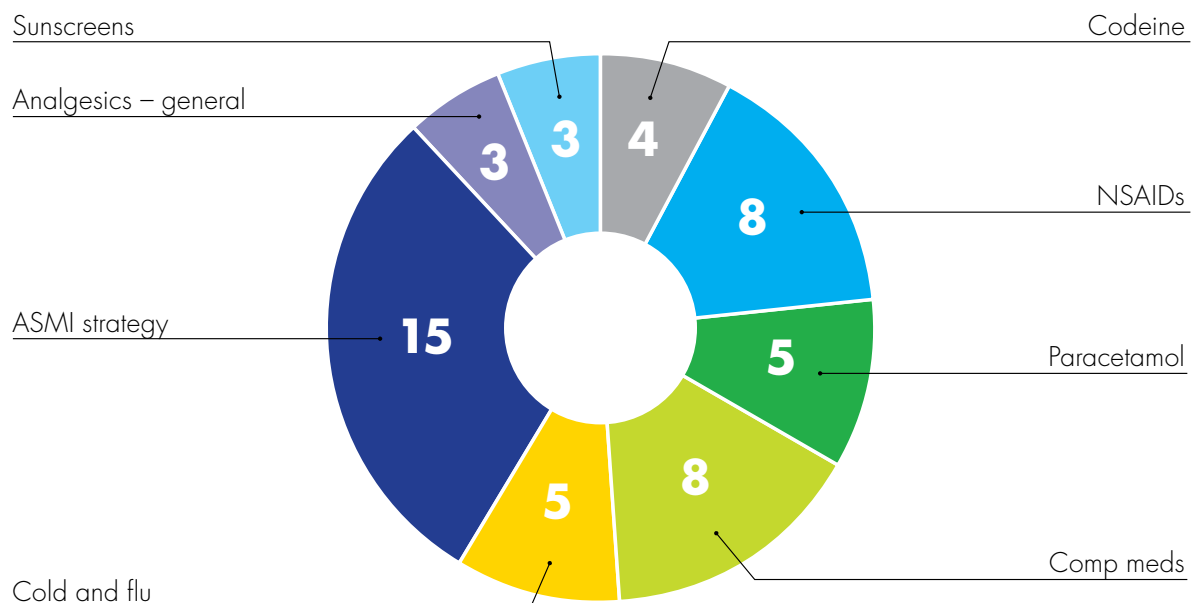
The key media issues ASMI managed during the last year are: the efficacy and safety of NSAIDs, paracetamol, complementary medicines and cough and cold medications and the debate around the up-scheduling of OTC codeine medicines. ASMI also promoted its S3 advertising research and strategic position on the scheduling policy framework in the media (Figure 2).

This year saw increased concern about the power of social media to drive negative reports in all media channels, in particular, reports of sunscreens ‘not working’. ASMI informed consumers about the official channels for reporting adverse effects via consumer and social media and will continue this communication approach in Australia’s summer months.

One of the issues ASMI set out to address in the last year is the adverse media coverage of non-prescription medicines. ASMI shared a range of information resources with journalists and encouraged them to refer to them when researching stories about OTC and complementary medicines. This approach will continue in the coming year, particularly in the consumer media.

In the next 12 months, ASMI anticipates significant media activity in the areas of OTC codeine and combination analgesics, sunscreens, e-cigarettes and complementary medicines. ASMI will proactively manage these issues to inform the media conversation, represent the industry’s position on policy issues and promote self care. ASMI will also continue to reinforce in the media the contribution the sector makes to Australia’s economy.

**Figure 2**  
ASMI media issues by topic





# Targeted Use of Complementary Medicines: Potential Health Outcomes & Cost Savings in Australia



FROST & SULLIVAN

A Frost & Sullivan Economic Report  
Christopher Shanahan, M.S.  
Robert de Lorimier, Ph.D.



# Non-Prescription Products — Industry Overview



## Driving regulatory reform

In a time of unprecedented regulatory reform, ASMI continues to work with members, the TGA and other stakeholders to ensure outcomes are practical, proportionate, effective and implemented within a realistic timeframe.

### Review of Medicines and Medical Devices Regulation

ASMI lodged numerous submissions in the last year to the consultation process for reform of Medicines and Medical Devices Regulation (MMDR). ASMI's submissions represented the industry's position on advertising reforms, scheduling policy, S3 advertising, complementary medicines, low-risk therapeutic goods, advertising complaints, sanctions, penalties and strengthened medicines monitoring.

ASMI is pleased that in the government's response to the 58 recommendations, only three were inconsistent with the industry's position (S3 advertising, advertising pre-approvals and the TGA's label "claimer" for certain listed medicines). ASMI continues to work with members, stakeholders and the TGA to ensure that the MMDR reforms are practical, proportionate, effective and implemented within a realistic timeframe.

### Codeine Rescheduling

The TGA's final decision to up-schedule all codeine-containing medicines to prescription only from 1 February 2018 was published on 20 December 2016. ASMI explored various alternative proposals and the potential mechanisms for reviewing the decision. With ASMI's encouragement, the TGA held an industry forum and co-ordinated a national labelling exemption program with the States and Territories. ASMI continues to work with members, professional bodies, consumer groups, State Health Departments, TGA and other stakeholders to ensure a smooth transition.

### Labelling and Packaging

Non-prescription medicine labels are the single most important source of information for consumers about the safe selection and use of these products. For non-prescription medicines, brand recognition particularly matters as consumers generally shop by brand and the condition for which they are seeking medication.

Revised Therapeutic Goods Orders and guidelines were introduced in August 2016, which incorporated many of the industry's proposals and were substantially different from the TGA's initial proposals. Since that time, ASMI has continued to work with members and the TGA to resolve issues with the new Orders.

### Country of Origin Labelling

ASMI is pleased the final outcomes of the country of origin labelling reforms for therapeutic goods reflect the industry's position. There will be no mandatory labelling requirements for therapeutic goods and the test for compliance has been simplified for all products.

### List of Permitted Ingredients for Listed Medicines

With ASMI encouragement, the TGA improved the usability of the List of Permitted Ingredients for Listed Medicines. ASMI continues to work closely with members and with the TGA to identify further process improvements.

The ASMI Secretariat and ASMI membership monitored and contributed to various other reforms including proposals in relation to scheduling of medicines and poisons, pharmacy regulation, intellectual property, sunscreens, good manufacturing practice, RASML and TGO78.

In all responses, ASMI has been ever mindful to ensure reforms in both Australia and New Zealand retain the current trans-Tasman alignment for supply of a common product in both markets.





## Building the evidence base supporting self care

During 2016–17, ASMI commissioned the Centre for Health Economics Research and Evaluation at the *University of Technology Sydney (CHERE)* and *Macquarie University Centre for Health Economics (MUCHE)* to conduct research studies to better build the evidence base to support greater self care.

### Advertising Pharmacist Only (S3) Medicines

In 2016, CHERE conducted a randomised control study to assess the impact of a 'mock S3 product TV advertisement on consumer and pharmacist behaviours and health outcomes. The study involved 1300 consumers, 500 pharmacists and 500 pharmacy assistants.

The research findings are tremendously encouraging as they indicate better quality use of medicines outcomes for the consumer with advertising than without it. The CHERE research dispels myths currently held about S3 advertising. S3 advertising increases consumer awareness of therapeutic options and pharmacy services and drives more health conversations between pharmacists and consumers. Consumers in the study were comfortable with pharmacists determining whether the advertised S3 product was suitable for them and pharmacists appropriately triaged consumers, recommending a suitable course of action if the advertised product was not appropriate treatment (e.g. referral to a GP or recommend an alternate product). The CHERE research supports the industry's position that consumer advertising for the vast majority of S3 products is appropriate and will drive better healthcare outcomes.

### Complementary Medicines Evidence Forum – Next Steps

Public discourse about the evidence supporting the efficacy of complementary medicines is polarised. ASMI and the National Institute for Complementary Medicines (NICM) convened a forum of 20 academics eighteen months ago to discuss this issue and explore ways of enabling a more constructive public discourse around complementary medicines. ASMI and NICM commissioned two independent researchers to draft three papers coming out of the forum. The first, to be published in late 2017, is a discussion paper highlighting the forum's key themes and questions. The second will provide guidance on the next steps in facilitating a more constructive public discourse and the third paper will provide a platform for specific actions.

### Health Economic Framework for Switch

During 2016 and 2017 MUCHE has been developing a health economics model for prescription only to S3 switch. The model aims to provide a framework to evaluate the potential health economic impacts of a switch. It can be used by switch initiators when they apply for the switch of a molecule and by regulators to assist decision making when they assess a switch application. MUCHE tested the model with triptans and oral contraceptives to assess whether it accurately captured the health economic impacts of switching these molecules and results of this testing as well as the model itself, will be shared at the WSMI Global Assembly in October.





## Forming alliances to advance the self care agenda

In 2016, ASMI spearheaded a Self Care Alliance Steering Group, along with several other organisations and individuals with an interest in self care. The Steering Group agreed that foundational research could provide the basis to take self care initiatives forward. HCF, Remedy Healthcare and ASMI commissioned the Health Policy Collaboration Unit at Victoria University to conduct the research, which involves an environmental scan and analysis of the state of self care in Australia. Victoria University is also conducting a terminology review. This research will help the Steering Group to determine priority projects and initiatives for the Self Care Alliance.



## Global platform for policy focus

### WSMI General Assembly

One of the most exciting aspects of ASMI hosting the WSMI General Assembly this year is that it provides a global platform to launch, share and debate the latest research with global thought leaders about the role of self care in healthcare policy. CHRE's S3 research and MUCHE's model of assessing the health economics of switch will be launched, as will overseas research about OTC models and minor ailment schemes. This research will build the evidence base to support an expanded role for self care in Australia and around the world. It will be a catalyst for engaging more deeply with government and stakeholders about what else can be done to drive greater self care. It will also be the catalyst for ASMI to drive a national debate and advocacy about the crucial role self care plays in healthcare policy.









## 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 2016 and 30 June 2017 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 207 items were reviewed, of which 77 were found to contain one or more possible breaches of 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 high.

A significant percentage of the breaches recorded related to the mandatory statements that are required when advertising therapeutic goods. The statements are required to be prominently displayed so as to be easily read from a reasonable viewing distance. In the material found to be in breach of the *TGAC* or *ASMI Code of Practice*, these statements were sometimes inadequately displayed or sized. Also, some materials had inconsistent, incorrectly placed, missing or incomplete mandatory statements.

Other breaches were noted for use of the term 'ideal', which may arouse unwarranted expectations; the use of out of date sales data to claim #1; concerns were raised over the body of evidence supplied for some claims and the accuracy of claims in one product; the use of a restricted representation; and the advertisement of a prize directed at children and therefore not a quality use of medicine.

## Complaints Panel Determinations

There were no complaints heard or determined this year.





# The ASMI Board

## Board of Directors



**Robert Barnes,**  
Aspen Australia



**Doug Cunningham,**  
Johnson and  
Johnson Pacific



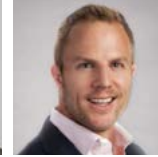
**Lindsay Forrest,**  
Consultant  
(Chairman)



**Lisa Golden,**  
Apotex



**James Jones,**  
Takeda  
Pharmaceuticals  
Australia  
(Secretary)



**Sandy Mellis,**  
RB (from  
November 2016)



**Alan Oppenheim,**  
Ego  
Pharmaceuticals

## ASMI Board Composition

The ASMI Board composition, nominations, 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 (the Elected Directors)
- Up to four Directors appointed by the Board (the 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



**Elizabeth Reynolds,**  
GlaxoSmithKline  
Consumer  
Healthcare



**Paul Rose,**  
Pfizer Consumer  
Healthcare  
(Vice-Chair)



**Mark Sargent,**  
Bayer Australia

the three Director positions to be vacated. In this way ASMI ensures 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 current ASMI Elected Directors are:



**Robert Barnes,**  
Aspen Australia



**Lisa Golden,**  
Apotex



**Sandy Mellis,**  
RB (from  
November 2016)



**Elizabeth Reynolds,**  
GlaxoSmithKline  
Consumer  
Healthcare



**Mark Sargent,**  
Bayer Australia

## The current ASMI Skills-based Directors are:



**Doug Cunningham,**  
Johnson and  
Johnson Pacific



**Lindsay Forrest,**  
Consultant  
(Chairman)



**James Jones,**  
Takeda  
Pharmaceuticals  
Australia  
(Secretary)



**Alan Oppenheim,**  
Ego  
Pharmaceuticals

# ASMI – Your *Extended* Support Team



## ASMI Member services



### Advice and Support

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



### Shaping Industry Initiatives

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



### Member Events

- World Class Annual Industry Conference
- Round table dinner/ breakfasts
- Education Seminars
- Online Training
- Members Forums/Meet the ASMI board
- Parliamentary events
- ASMI Excellence Awards.



### Advocacy and Representation

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



### Staying informed

- Keep up to date on issues
- Surveillance locally and internationally with share-out of issues to members
- E-newsletters, Alerts, Events, Seminars, Workshops, web portal.



### Member Training

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



### Self Regulation

- ASMI Code
- ASMI Complaints Panel
- Promotional Monitoring Panel.



# ASMI – Your *Extended* Support Team

## ASMI Member secretariat





**Emi Gosling**  
Advertising Services  
Manager  
02 9923 9405



**Judith Brimer**  
Executive Officer  
TGACC and CRP  
02 8667 3025



**Sarah-Jane Leon**  
Advertising Services  
Manager  
02 9923 9405



**Josie Barisic**  
Executive Administrator  
TGACC and CRP  
02 8667 3025

### ASMI advertising services office (TGA contracts)



# ASMI: Representing the Australian Non-Prescription Products 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 latest information and intelligence from diverse sources and disseminate it to our Members to alert them to potential issues that may affect their business.

ASMI is a member of the World Self Medication Industry (WSMI) and our Chairperson and CEO are on its Board. 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 Organisation (WHO). Our membership of WSMI enables us to track and contribute to international trends and developments in consumer healthcare.



Australian Self Medication Industry

## General Enquiries:

Suite 2202, Level 22  
141 Walker St,  
North Sydney NSW 2060

**Ph: +61 2 9922 5111**

Fax: +61 2 9959 3693

[info@asmi.com.au](mailto:info@asmi.com.au)

[www.asmi.com.au](http://www.asmi.com.au)

## ASMI Membership Enquiries:

Membership Services – ASMI

**Ph: +61 2 9923 9403**

Fax: +61 2 9959 3693

[info@asmi.com.au](mailto:info@asmi.com.au)

## Media Enquiries:

Communications Manager – ASMI

**Ph: +61 2 9923 9410**

Fax: +61 2 9959 3693

[info@asmi.com.au](mailto:info@asmi.com.au)