ASMI

2015–16 ANNUAL REPORT

Advancing consumer health through responsible self care

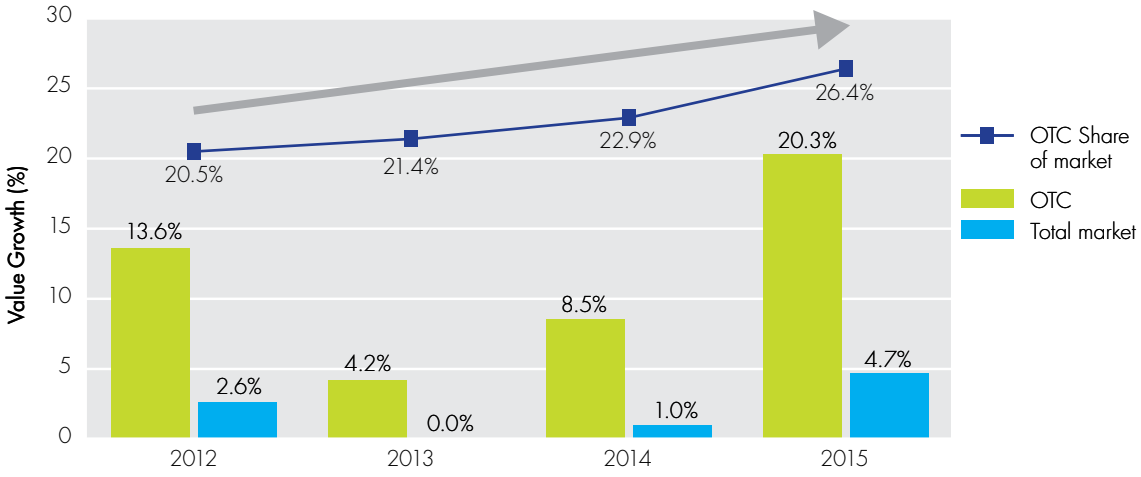
Industry Snapshot

Non-Prescription Products Industry

- Contributes approximately $2.1 billion toward local manufacturing[1]
- Exports approximately $1 billion p.a.[2] and growing strongly
- Approximately 16,000 registered (AUST R) and listed (AUST L) products on the ARTG[3]
- Every $1 spent on the top 8 non-prescription product categories saves the Australian economy $4.[4]

Consumer Healthcare growth outpaces Prescription

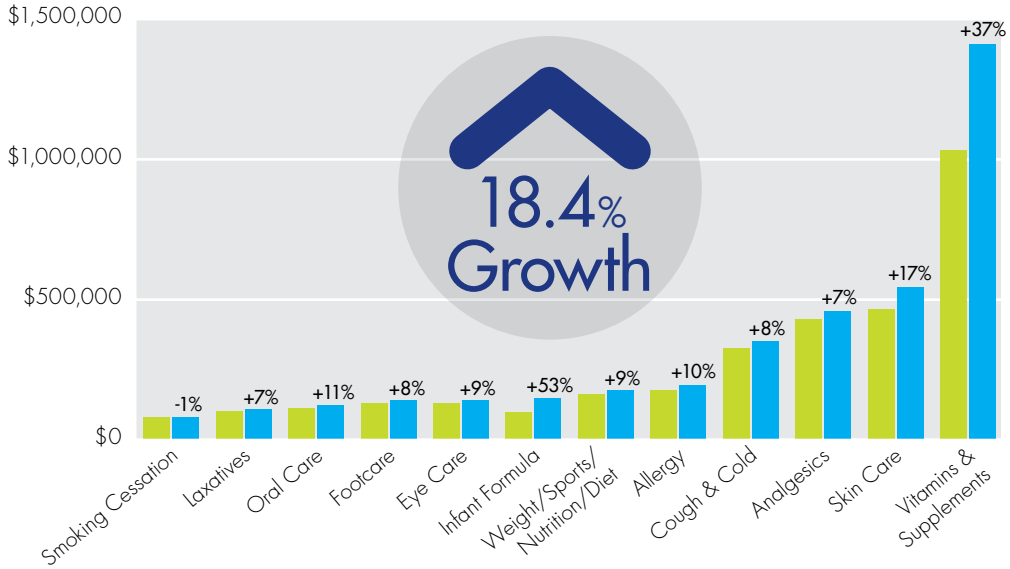
Growth of the OTC market vs. Total market



Source: IMS National Audits (API+AHI) – ex-wholesaler list price – MAT December 2015.

Top 12 pharmacy front of shop categories

2014 vs 2015



Source: IRI Pharmacy Retail Scan.

1 IBIS Pharmaceutical Product Manufacturing in Australia, March 2014. IBIS World, Pty Ltd.
2 IBIS Pharmaceutical Product Manufacturing in Australia, March 2014. IBIS World, Pty Ltd.
3 TGA Half Yearly Performance Report (March 2015)
4 The Value of OTC Medicines in Australia (March 2014) Macquarie University – MUCHE Report.

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CEO's and Chairperson's Message

Lindsay Forrest

Deon Schoombie

Driving Regulatory Reform

This year the Expert Panel conducting the *Review of Medicines and Medical Devices Regulation* made 58 recommendations for reforms impacting prescription medicines, generic medicines, over-the-counter (OTC) medicines, complementary medicines and devices. The majority of the recommendations were consistent with ASMI's position; however, we do not support the recommendations to retain restrictions on S3 advertising and to replace the current mandatory advertising pre-approvals system with a self-regulatory system.

Retaining Consumer Access to OTC Codeine Medicines

During the last 12 months ASMI drove an intense advocacy and media campaign to retain the current S3 scheduling of OTC codeine medicines. The Government's interim decision to up-schedule all OTC codeine medicines was put on hold while it undertook further public consultation on the issue. A final decision has not yet been announced advocacy efforts are continuing to address the threat to the OTC status of the medicines. We are working with the Pharmacy Guild of Australia to implement a real-time monitoring system for OTC medicines containing codeine. ASMI and the Guild co-developed the system and ASMI provided funding for the development and roll-out of the system in community pharmacies across Australia.

Advancing Self Care

The Self Care Alliance is gaining momentum as it brings together key healthcare stakeholders to raise the prominence of self care in the national healthcare policy. ASMI continued to support the Self Care Alliance during 2015, to raise its profile and establish it as an independent body.

Consistent with the strategic objective to support policy positions and to expand the evidence base for self care, three studies were commissioned in the past year, i.e. an economic framework to support switch (Macquarie University Centre for the Health Economy); research to support ASMI's proposal for S3 advertising reforms (University of Technology Sydney Centre for Health Economics Research and Evaluation), and the health-economic benefits of complementary medicines (Frost and Sullivan).

Planning for the WSMI General Assembly in 2017

In October 2017 ASMI and NZSMI will be co-hosting the World Self Medication Industry General Assembly, which will focus on the health economics of self care. The three-day conference will showcase evidence-based models supporting enhanced self care, and the role of non-prescription medicines in individual and public health. On the second day of the Assembly the Therapeutic Goods Administration (TGA) will host a Regulators Forum where regulators from around the world will discuss the unique challenges in relation to the regulation of non-prescription medicines.

We would like to thank ASMI members for their contributions via the ASMI Board, subcommittees and working groups as well as the ASMI secretariat staff for their commitment to supporting ASMI members and advancing the interests of industry.

Lindsay Forrest
ASMI Chairperson

Deon Schoombie
CEO

1. Setting the Industry Agenda

The OTC and complementary medicines sector requires a regulatory framework balancing consumer protection with an operating environment that incentivises R&D, investment in new products, services, local manufacturing, employment and export growth. The level of regulation should be commensurate with the risk posed by the regulated products, with the aim of aligning with the COAG principle of 'minimum effective regulation'.

ASMI is advocating for a suite of measures that will incentivise investment and innovation in the non-prescription medicines sector through increasing consumer access to medicines. This will contribute to reducing Medicare and PBS costs, leading to improved health outcomes and increased sustainability of the Australian healthcare system.

In its 2016 Pre-Budget submission, ASMI recommended three areas of regulatory reform to remove barriers to investment and innovation:

Strengthen Intellectual Property Protection

OTC and complementary medicines do not benefit from the same level of intellectual property protection as do prescription medicines. Currently there is no provision for data protection in relation to these medicines and where competitors benefit from the data generated by the innovator, the latter is placed at a significant commercial disadvantage.

ASMI is advocating for the introduction of data protection and market exclusivity provisions for OTC and complementary medicines to ensure investment in innovation is rewarded.

Allow Advertising of Pharmacist Only (S3) Medicines

The *Medicines and Medical Devices Regulation* is for the Federal Government to retain its restrictions on the advertising of S3 medicines. This prohibits consumer awareness for many of these medicines, which means consumers may continue to consult GPs for conditions which could be safely managed by pharmacists. It also stifles investment in innovative switches.

ASMI is proposing an alternative regulatory model for direct-to-consumer communication of S3 medicines. Counselling by the pharmacist is a key aspect of the model, which also includes information about the symptoms and/or condition; and product specific information.

The Centre for Health Economics Research and Evaluation (CHERE) at the University of Technology, Sydney is undertaking research to measure the impact of this alternate model of S3 consumer communication on the behaviour of pharmacists, pharmacy assistants and consumers, and results will be available by the end of 2016.

Reshape the Scheduling Environment

ASMI is advocating for the adoption of a comprehensive and coordinated multi-stakeholder review of the Australian scheduling policy framework to support the National Medicines Policy.

2. Advancing Self Care

One of ASMI's key strategic objectives is to support and promote responsible self care in Australia. Self Care, also sometimes referred to as Self Management or Shared Care, does not mean "no care". Rather, it is about putting the individual in the centre and reimagining the healthcare sector in ways that empower and support people to take responsibility for their own health and wellness and that of their family.

Self Care Alliance – A Collaborative Approach

Implementing self care is beyond the capacity of Government to mandate or any single group to bring about. It requires input and action by participants from all aspects of the health sector, i.e. consumers, healthcare professionals and other providers, researchers, educators, policy makers, public and private funders and industry.

The Self Care Alliance has been set up to be the neutral space for all of these parties to come together to pool knowledge and expertise, to foster dialogue, and facilitate and initiate collaborative efforts to support the implementation of self care in the Australian health and care sector. The vision is that it will become the 'go to place' for expertise and advice about self care in Australia.

The primary aim of the Self Care Alliance is the adoption of self care as a core element of a sustainable national health care system for Australia.

Guiding principles of the Self Care Alliance include:

- Person-centred focus
- Evidence-based solutions
- Collaborative partnerships
- Empowered citizens.

ASMI continues to support the Self Care Alliance to advocate for self care to become an integral part of the national healthcare policy. In the past 12 months, ASMI has provided in-kind and financial support to the Self Care Alliance to help build the support base, facilitate stakeholder presentations, and assist the formation of the Alliance into a stand-alone, independent entity.

ASMI facilitated the Alliance's first Roundtable Discussion, ''The Role of Technology in Self Care', as well as the development of a website for sharing of research, learnings and updates, both locally and globally.

3. Building the Evidence Base

During 2015 ASMI continued to build the evidence base for OTC and complementary medicines to inform the policy and advocacy agenda, and support industry growth.

Research on Impacts of S3 Advertising

The UTS Centre for Health Economics Research and Evaluation (CHERE) is conducting research to demonstrate the impact of ASMI's proposal for an alternative regulatory model for S3 advertising on consumers, pharmacists and pharmacy assistants. The results of this study are intended to support ASMI's advocacy to remove the restrictions on the advertising of S3 medicines.

Health Economics Study

ASMI commissioned the Macquarie University Centre for Health Economics (MUCHE) to develop a health economic framework that would demonstrate the benefits of non-prescription medicines to better inform decisions in relation to the scheduling of medicines.

This research will be presented at the World Self Medication Industry (WSMI) General Assembly, which ASMI and NZSMI are co-hosting in Sydney in October 2017. The research model is intended to be reproducible in different international jurisdictions, so it is likely other WSMI members will use the same methodology to assess the economic benefits of self care in their local settings.

Economic Benefits of Complementary Medicines

In 2015 ASMI continued to build the evidence base for complementary medicines. Previously ASMI engaged Frost and Sullivan, a US research company, to conduct a study assessing the potential economic benefits of complementary medicines usage in Australia. The study initially examined six complementary medicines regimens, all with evidence of efficacy, across four chronic disease conditions osteoporosis, cardiovascular disease (CVD), age-related macular degeneration and depression. The report was very well received and continues to be referenced by various organisations in Australia to support the role of complementary medicines. To build on this, in 2015 Frost and Sullivan assessed two further conditions and the first of these studies on zinc has been completed, and will be published during 2016.

Evidence Forum

ASMI initiated the first ever 'Evidence Forum' in November 2015 to provide new direction for evidence in complementary medicines. The forum brought together 20 thought leaders in complementary medicines from research universities and the community sector to define key issues around evidence on complementary medicines. Topics included the appropriateness of various types of research; consumers' rights around access to complementary medicines, and the role and status of traditional evidence.


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
AUSTRALIAN SELF MEDICATION INDUSTRY
ASMI
Non-Prescription Produc
– Industry Overview

4. Regulatory Reforms

ASMI had several policy successes during 2015, including: deferral of the final decision on scheduling of OTC codeine; many of the 58 recommendations of the Expert Panel *Reviewing of Medicines and Medical Devices Regulation* were consistent with ASMI's position; several proposed labelling reforms are aligned with ASMI's position; and positive outcomes on OTC Business Process Reforms and TGA fees.

Review of Medicines and Medical Devices Regulation

The Expert Panel Review of Medicines and Medical Devices Regulation published its recommendations in 2015. ASMI is pleased that of the 58 recommendations, only five were inconsistent with the industry's position. Notable exceptions being the retention of restrictions on S3 advertising, the requirement for disclaimers for listed medicines, and replacement of the current mandatory advertising pre-approvals system with a self-regulatory system. We are now awaiting the Commonwealth Government's response to the recommendations.

Codeine Re-scheduling

ASMI continues to oppose the re-scheduling of OTC codeine medicines. Instead, ASMI supports a package of targeted measures, including a real-time monitoring system, together with mandatory label warnings, reduced pack sizes, and education. ASMI also supports separate regulatory approaches for codeine-containing cold and flu products and codeine-containing analgesics as there is no evidence of misuse of codeine containing cold and flu medicines. Together with the Pharmacy Guild of Australia, ASMI has co-developed and co-funded medsASSIST, a real-time monitoring system for OTC codeine analgesics, which was rolled out in pharmacies nationally in March 2016. We await the Commonwealth Government's final decision on the scheduling of OTC codeine medicines.

Labelling and Packaging

The new Therapeutic Goods Orders and guidelines incorporate many of the industry's proposals and are substantially different from the TGA's initial proposals. The new labelling orders are risk based, pragmatic and come with a practical 4 year transition period to minimise the regulatory burden.

Country of Origin Labelling

Initial reforms to Country of Origin Labelling (COOL) aimed at food labelling threatened to spill over into other areas such as therapeutic goods. ASMI's position is that therapeutic goods should be exempt from COOL requirements because they are already subject to strict labelling regulations. ASMI is pleased that, following an extensive consultation, the Government will exempt therapeutic goods from COOL requirements.

International Harmonisation of Ingredient Names

The TGA is implementing a project to harmonise Australian ingredient names with international conventions. This reform will impact regulatory data, product information and product labelling. ASMI is pleased the TGA has accepted our recommendation to time the implementation and transition period to coincide with the labelling changes of the new Labelling Orders, minimising the cost of compliance.

List of Permitted Ingredients for Listed Medicines

ASMI advocacy has focused on promoting regular updates to provide predictable timeframes for addressing identified errors and incorporating newly approved listed ingredients, ensuring transparency of change controls and historical data, and supporting the improvement of identified user-interface issues.

5. Leading on Issues Management

ASMI proactively manages issues to inform the public debate, facilitate balanced reporting by the media, and minimise reputational risk for the industry. It also proactively promotes the industry to build its profile and reputational capital.

Scheduling of OTC Codeine Medicines

During the last twelve months ASMI conducted an intensive media and advocacy strategy against the proposed up-scheduling of OTC codeine medicines. ASMI participated in several media interviews about its submissions to the ACMS review and published several opinion pieces, calling for the retention of the current scheduling of OTC codeine medicines. ASMI reinforced its support for a package of targeted measures to reduce the risk of OTC codeine misuse, including a real-time monitoring system, reduced pack size, mandatory warning labels and increased pharmacist and consumer education.

Review of Medicines and Medical Devices Regulation

ASMI advocated for reform of scheduling policy; removal of restrictions on S3 advertising, and streamlining of complementary medicines regulations in several media statements and opinion pieces regarding the Expert Panel's *Review of Medicines and Medical Devices Regulation*.

OTC Analgesics

OTC analgesics received substantial media coverage throughout the year. Media issues managed during the year included the use of OTC analgesics during pregnancy; children's use of OTC analgesics; labelling; analgesic overdoses, and OTC NSAIDs. Many of the issues involved the possible side effects of analgesics when taken at high doses for prolonged periods of time. ASMI reaffirmed that OTC analgesics are for short term use for mild to moderate pain and when taken according to the recommended dose have a well-known safety profile.

Complementary Medicines

A key issue managed repeatedly during the year related to the regulation of complementary medicines. In its media responses to these issues ASMI reinforced that Australia has one of the most highly regulated complementary medicines industries in the world. Other issues related to the efficacy and safety of complementary medicines, labelling, active ingredients, interactions with prescription medicines and investment in complementary medicines research.

6. Priorities for the Next 12 Months

During the next 12 months ASMI will continue to advance the self care agenda and advocate for regulatory reform to increase access to medicines and provide incentives for industry to invest and innovate. Priority areas of regulatory reform are the regulatory framework for OTC and complementary medicines, scheduling and S3 advertising. Work will continue on current regulatory reforms.

Advancing Self Care

ASMI will continue to play a leading role in the Self Care Alliance as it advocates for self care to become an integral part of the national healthcare policy. The key focus for the Self Care Alliance in 2016 is to become an independent not-for-profit body, with a membership and governance model that will sustain it into the future.

Continuing to Build the Evidence Base

ASMI will continue to build the evidence base through three key research studies:

- Building the case for prescription to OTC switch and S3 advertising
- The economics of self care
- Frost and Sullivan study, *Economic Analysis of Complementary Medicine Usage in Australia*. Studies on zinc and the common cold and chromium for diabetes will be launched.

Advocating for Best Practice Regulation

With the delay in the Federal Government releasing its response to the recommendations of the Expert Panel *Reviewing of Medicines and Medical Devices Regulation* and the sense of uncertainty in the regulatory environment, ASMI will continue to advocate for a risk-based approach to therapeutic goods regulation and medicines advertising, together with improvements in the complaints handling process, enhancing consumer awareness of S3 medicines by reforms to S3 advertising, for scheduling reform, and for data protection to incentivise research.

ASMI is also ensuring industry representation in preparation for upgrades to TGA IT infrastructure, adoption of the next update to the PIC/S Guide for GMP for Medicinal Products including risk-based interpretive guidance for areas specific to the Australian regulatory framework, implementation of a transparent, predictable application pathway for registered complementary medicines based on clarity of requirement, and reforms to improve efficiency of the TGA's GMP inspection program.


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7. Promoting 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 four times between 1 July 2015 and 30 June 2016 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 422 items were reviewed, of which 164 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*, often these statements were inadequately displayed or sized. Some materials had inconsistent, missing or incomplete mandatory statements.

Other breaches were noted for an implied HCP endorsement with a product being used in a particular hospital; the use of out-of-date sales data in claims of #1; testimonial claims that did not illustrate typical cases; claims that may arouse unwarranted expectations due to the use of terms such as "cure", "break free", and "solution"; and claims that a product was a range leader, where there were very few competitors.

Complaints Panel Determinations

There was one complaint this year regarding Nuromol. The full determination is published on the ASMI website, but can be summarised as follows:

Nuromol

In July 2015, the Panel considered a complaint from AFT Pharmaceuticals Pty Limited ("AFT") about Nuromol advertisements by Reckitt Benckiser (Australia) Pty Limited ("RB").

The advertisements appeared in a range of media and included a number of claims about which complaints were made.

As a preliminary jurisdictional issue, the Panel determined that industry generated complaints could be lodged by non-ASMI members such as AFT.

The Panel found moderate breaches of the ASMI Code in relation to claims made about the absorption and efficacy of the Nuromol product as well as to claims made about the efficacy of a competitor product.

The Panel required RB to cease publication of the representations found in breach, to circulate a corrective statement, to cease distribution and destroy existing stocks of the materials and to pay a fine of $20,000.

Board of Directors

Robert Barnes, Aspen Australia

Shane Byrne, Perrigo (until March 2016)

Brett Charlton, Sanofi-Aventis Consumer Healthcare (until November 2015)

Doug Cunningham, Johnson & Johnson Pacific (from February 2016)

Lindsay Forrest, Consultant (from October 2015)

Lisa Golden, Apotex (from November 2015)

James Jones, Takeda Pharmaceuticals Australia

Phil Lynch, Johnson & Johnson Pacific (until January 2016)

Alan Oppenheim, Ego Pharmaceuticals

Elizabeth Reynolds, GlaxoSmithKline Consumer Healthcare (from August 2015)

Paul Rose, Pfizer Consumer Healthcare

Mark Sargent, Bayer Australia

Executive

ASMI Chairperson, **Lindsay Forrest** (from January 2016)

Secretary, **James Jones** (from January 2016)

Vice Chairperson, **Paul Rose** (from August 2015)

ASMI Chairperson, **Mark Sargent** (until November 2015)

ASMI Secretariat

Brenda Davy, Strategy Manager Complementary Medicines

Emi Gosling, Advertising Services Manager

Catherine Gwynne, Regulatory & Technical Manager – OTC Medicines

Claire Johnston, Member Events and Services Associate (until December 2015)

Marie Kelly-Davies, Communications Manager (until June 2016)

David Low, Member Events and Services Associate (from January 2016)

Filomena Maiese, Marketing & Business Development Director

Benison O'Reilly, Advertising Services Manager (until June 2016)

Steve Scarff, Regulatory & Scientific Affairs Director

Annaliese Scholz, Regulatory & Technical Manager – Complementary Medicines

Robyn Shiralli, Executive Assistant

Deon Schoombie, Chief Executive Officer

Julie Viatos, QUM Manager

Lily Villyas, Financial Controller

Janet Zanetti, Office Manager

Sarah-Jane Leon (from June 2016)

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.

ASMI

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