2018–19 ANNUAL REPORT





Advancing consumer health through responsible self-care

CHP Australia Purpose, Vision & Mission

Our members are manufacturers and distributors of consumer healthcare products, which include nonprescription medicines. CHP Australia also represents businesses that support the industry. These include advertising agencies and PR firms as well as legal, statistical and regulatory consultancy companies and individuals.

PURPOSE

MISSION

To promote and develop the Australian consumer healthcare products industry and to help members thrive. To enhance the health and well-being of Australians through access to proven healthcare products.

VISION

Consumers have the information and products to practice self-care with confidence.

CHP AUSTRALIA STRATEGIC GOALS 2018–2021

VOICE

Relevant and influential voice in Canberra and broadly

REBRAND

As a consumer healthcare products industry association

MANUFACTURERS

Have the representation and services they need







REPUTATION

Of member companies and our industry is protected



COLLABORATION

CHP extends influence and effectiveness through collaboration



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Chairman & CEO's Message



Lindsay Forrest



Deon Schoombie

There were two significant milestones in the past year. The company was rebranded from the Australian Self Medication Industry (ASMI) to Consumer Healthcare Products Australia (CHP Australia) and the second was the relocation of the offices to St Leonards after more than 3 decades in North Sydney.

The name change was very well received by members and stakeholders alike and the general view is that the new name better reflects the nature and business of our industry. Like most of our members, if not all, we need to maintain a keen focus on containing operating costs. The savings resulting from the relocation will better position us for future changes in 2020.

Through strong and effective advocacy CHP Australia achieved major reforms in the regulatory area following the review of Medicines and Medical Devices Regulations (MMDR). The main focus of our activities in the past year was to work closely with members and the TGA to minimise the disruption to business associated with the implementation of all the reforms, which impacted just about every aspect of the regulation of OTCs and complementary medicines.

Major wins occurred in the area of the scheduling policy framework, i.e. S3 advertising, streamlining business processes, the introduction of Appendix M and developing an Australian "switch agenda". Changes to the Therapeutic Goods Advertising Code and the new complaints handling process proved to be particularly challenging but through goodwill and close collaboration with the TGA significant improvements were implemented.

The business model for the self-regulatory advertising advisory service has been finalised and the service is scheduled to commence 1 July 2020 when the current mandatory pre-approval scheme is abolished.

Lindsay Forrest Chairperson

Ale Charatio

Deon Schoombie Chief Executive Officer

Gaining broad recognition of the value of self-care in a sustainable healthcare system remains a key strategic objective for us, including the industry's world body, the Global Self-Care Federation and our counterparts across the globe.

The Self-Care Alliance (SCA), which we spearheaded some years ago, is now under the auspices of Professor Rosemary Calder at Victoria University (Australian Health Policy Collaboration) and the Mitchell Institute. The SCA now has an expanding support base and this is a giant step towards adopting self-care in a national health policy.

Over the past year we have refocused our advocacy activities on improving health literacy, which is one of the key enablers of self-care. Building on our earlier collaboration with Life Education to support health literacy of primary school kids, we have entered into a renewed partnership, and with the focus this time on creating awareness about the importance of self-care amongst parents and teachers.

Our achievements over the past year were made possible by the unwavering support and investment of members as well as the secretariat. We thank them for that and we are looking forward to members' continued support to advance the consumer healthcare products industry.

A New Beginning



In June 2019, ASMI (Australian Self Medication Industry) rebranded to Consumer Healthcare Products Australia (CHP Australia).

Our members unanimously endorsed the change of our name and brand in April 2019.

The name Consumer Healthcare Products Australia better represents the industry in which our members operate. It also brings us in line with our international counterparts, CHP Canada and CHPA in America. Our launch event in June was well attended and it was a perfect opportunity to announce our partnership with Life Education and have Healthy Harold in attendance! Feedback from stakeholders about our new brand has been overwhelmingly positive.

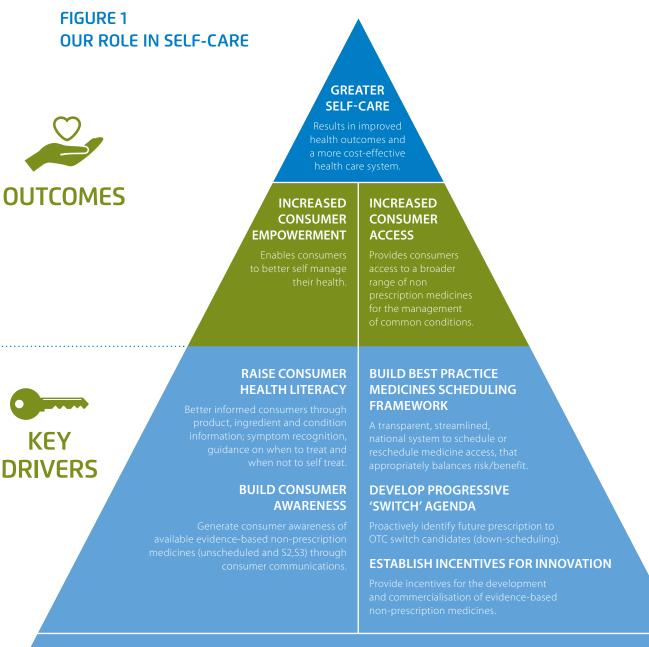


VOICE OF INDUSTRY

Setting the Industry Agenda

THE ROLE OF SELF-CARE

CHP Australia advocates for self-care to be elevated in national health policy, to contribute to improved health outcomes and a more cost-effective health care system. Self-care entails individuals taking greater personal interest in, and responsibility for, their health and well-being through practices including lifestyle, responsible use of medicines, diet and exercise. Increased consumer empowerment and access to medicines are key aspects to enabling greater self-care. CHP Australia, as illustrated below (Figure 1), is uniquely placed to facilitate action in these areas.



UNDERPINNED BY A STRONG REGULATORY SYSTEM WITH 'CHECKS AND BALANCES' TO PROTECT CONSUMERS

©CHP Australia (Consumer Healthcare Products Australia)

ADVOCATING FOR INCREASED CONSUMER ACCESS TO MEDICINES AND BALANCED REGULATION

CHP Australia continued its advocacy for greater consumer access to nonprescription medicines after successfully influencing policy outcomes in several areas during the MMDR (Medicines and Medical Devices Regulation) review. Some key highlights include:

Scheduling Policy Framework

Following the successful update of the Scheduling Policy Framework, the Government has now established a multi-stakeholder Scheduling Working Group with the aim of developing a progressive switch agenda for Australia. We are actively representing the industry through this working group.

Switch

Through our advocacy and collaboration with stakeholders we have continued to advance a positive switch environment, with key contributions in relation to:

- IP protection for switch applications
- Modelling the economic value of switch
- Identifications and publication of potential switch candidates

S3 Advertising and Appendix H

After CHP Australia's strong advocacy, the Federal Government has changed the default position to allow advertising of Schedule 3 medicines; whereas previously it was only by exception. CHP Australia was successful in having a number of existing S3 substances added to Appendix H as a block to reflect the new advertising policy.

Appendix M

With the introduction of Appendix M, CHP Australia has continued to work with the TGA, members and key stakeholders to ensure that this reform fulfils its potential as an enabler for S4 to S3 re-scheduling.



Leading on Issues Management

As the voice of the nonprescription medicines industry, CHP Australia promotes the industry's policy platform, protects the sector's reputation and educates consumers about the responsible use of nonprescription medicines to support self-care.

Over 150 articles were published in the mainstream, industry and online media from our 30+ media statements. We were at the forefront of media issues with a voice on a variety of social media platforms. We provided media monitoring and surveillance across Australian and International media for members on key issues and ingredients. CHP Australia led media debate on key issues impacting the industry's goal to increase consumer access to medicines. Some of the key media issues CHP Australia managed were:

- the efficacy and safety of a range of OTC medicines (with a focus on analgesics),
- the efficacy of complementary medicines,
- the efficacy and safety of sunscreens,
- the debate about the impact of sunscreens on the environment,
- the scheduling environment, switch candidates and IP protection for switch applications,
- country of origin labelling, and the ongoing debate about the up-scheduling of OTC medicines.

CHP Australia continued to promote global and local research, including research that demonstrates the economic impact of greater consumer access to medicines and the benefits of increased focus on preventive health and self-care.





DRIVING REGULATORY REFORM

Driving Regulatory Reform

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

MMDR REVIEW

CHP Australia is continuing to work with the TGA and members to support the smooth implementation of the major regulatory reforms still coming out of the MMDR review.

In particular we were able to advance the industry agenda in relation to:

- Permitted indications
- Permissible Ingredients
- Market exclusivity for new listed ingredients
- Data protection for CM products
- Scheduling Policy
- Appendix M
- Appendix H
- Switch (economic modelling and the pro-active identification of candidates)
- Regulation of low-risk products.

THERAPEUTIC GOODS ADVERTISING CODE (TGAC)

Throughout the TGAC reform process, our advocacy has involved participation in the TGA consultations (public and targeted), advice to members, member workshops, meetings with the TGA and meetings with other stakeholders. As a direct result, we were able to achieve the following:

- A more practical version of the new Code
- A 12 month "grace period" after the new Code came into effect (to accommodate existing materials)
- Subsequent improvements to the Code
- Simpler and more pragmatic guidelines on the use of the term "natural".

ADVERTISING COMPLAINTS, SANCTIONS AND PENALTIES

New TGA enforcement powers came into effect in 2018. Through close contact with the TGA and other stakeholders, we have been able to keep members informed and have continued to advocate for a best-practice system with a focus on fairness, transparency, efficiency and effectiveness.

Our membership of the Therapeutic Goods Advertising Consultative Committee has allowed us to influence discussions and to obtain valuable insights for our members.

ADVERTISING COMPLIANCE SERVICE

We have developed a business model for a voluntary (self-regulatory) advertising advisory service to come into effect by 1 July 2020 to replace the mandatory pre-approvals system which will be abolished on 30 June 2020. This new comprehensive service will cover advice, compliance and assistance in the event of complaints, as well as ongoing education. The design of the voluntary service has been developed with the Marketing & Ethics Subcommittee, the Regulatory Policy Subcommittee and media compliance bodies.

COUNTRY OF ORIGIN LABELLING

We collaborated with all stakeholders to articulate the issues and identify solutions to the country of origin labelling requirements for all medicines. Input was sought from:

- Members
- The ACCC
- The NSW Department of Industry
- The Commonwealth Department of Industry, Innovation & Science
- The Australian Trade and Investment Commission (Austrade)
- Australian Made Campaign Limited (AMCL).

We are pleased to see that our suggestion for using s255(3) of the Australian Consumer Law (the ACL) has been taken into account and a satisfactory resolution is expected in early 2020.

THERAPEUTIC GOODS ORDERS (TGOS)

The transition to TGO92 remained a high priority for our members with the last year of the 4 year transition period ahead. We maintained close contact with the TGA and were able to assist members in relation to transition arrangements, umbrella branding issues, naming issues and allergen declarations. The following Therapeutic Goods Orders were due to "sunset" during the year and we were able to assist members by identifying issues, advocating for reform and achieving pragmatic transition arrangements:

- TGO54 which became TGO104 (Disinfectants)
- TGO77 which became TGO100 (Microbial Standards)
- TGO78 which became TGO101 (Tablets, Capsules and Pills)
- TGO82 which became TGO103 (Tampons).

OTHERS

We also provided advocacy and member assistance across a wide range of regulatory reforms, some of which included:

- Application of the new TGAC to Digital and Social Media
- PI/CMI reforms
 - The Listed Medicines Compliance Rating Scheme
- 2025 National Packaging Targets
- Trans-Tasman regulatory issues (e.g. labelling, scheduling, product safety)
- Device reforms.

COMPLEMENTARY MEDICINES EVIDENCE

CHP Australia previously 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 in the AIMA journal: Advances in Integrative Medicine Journal (Setting an agenda for strengthening the evidence-base for traditional and complementary medicines: Perspectives from an expert forum in Australia).

PROMOTING GREATER SELF-CARE

Developing A National Self-Care Policy



SELF-CARE ALLIANCE

CHP Australia spearheaded the establishment of the Self-Care Alliance in 2014 at Parliament House, Canberra, bringing together stakeholders with an interest in advancing self-care. In 2017, CHP Australia along with two foundation members of the alliance, HCF and Remedy Healthcare, commissioned the Australian Health Policy Collaboration (AHPC) at Victoria University to review self-care in Australia.

The leadership of the Self-Care Alliance and its drive for policy change is now being spearheaded by Victoria University. CHP Australia is a member of the steering committee which is responsible for securing financial support for the initiative. The health policy expertise at Victoria University will help take self-care to a new level as it pushes for self-care to be acknowledged as a component of our national health policy.

The landmark report entitled "The State of Self Care in Australia" (Australian Health Policy Collaboration (AHPC) at Victoria University) 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.





HEALTH LITERACY – A KEY ENABLER OF SELF-CARE

The basic foundation for responsible self-care is health literacy. An ABS (Australian Bureau of Statistics) 2006 study showed that only 40% of Australians had satisfactory health literacy levels.

In June 2019, CHP Australia announced a partnership with Life Education Australia to promote self-care and boost health literacy among Australian parents and teachers. For 40 years Life Education has been empowering children to make safe and healthy choices. Parents and teachers play a pivotal role in modelling healthy behaviours to children. It is important to arm them with the skills and knowledge they need to raise the next generation of healthy young Australians.

It is exciting to partner with an organisation as passionate as us about empowering Australians to improve their health and enhance their well-being.



ON THE WORLD STAGE – WORKING WITH THE GLOBAL SELF-CARE FEDERATION

The global body of the nonprescription medicines industry also had a name change in 2019. Previously known as the World Self Medication Industry (WSMI) it is now the Global Self-Care Federation (GSCF). CHP Australia is a member of the Executive Committee of the GSCF board and an active participant in various working groups.

THE FUTURE OF SELF-CARE

Responding to the rapid evolution of the external environment impacting consumer healthcare, GSCF invested in 2018 in a strategic analysis of the future of self-care to inform and augment GSCF's strategy and action plan to:

- Identify the key trends that will shape the self-care market over the next 5–10 years
- Determine how the future environment needs to look to enable growth of the self-care market
- Define actions GSCF could take at the global level to shape and amplify the work performed by regional/local organisations.

Three scenarios were identified for the future of self-care, telling challenging yet plausible stories of how the world might unfold. This led to the adoption of a new strategy for GSCF, called the "The Future of Self-Care". This strategy covers three main pillars or domains:

- Trust
- Healthcare system sustainability (self-care as a cornerstone of national health policies)
- Health data.

The GSCF will be undertaking a formal assessment of the nonprescription medicines industry's levels of trust and reputation with the key global and international stakeholders who influence the self-care environment.

Similarly, GSCF wants to gain a deeper understanding of the health data field as it relates to nonprescription medicines and self-care. Health data remains unstructured, incredibly complex and coupled with the added challenges of privacy and confidentiality. 'Big data' and 'Real World Evidence' is enabling the healthcare industry to transform patient care. At same time consumer habits towards managing their own health are changing – information and products are sourced through online platforms and e-commerce, making self-care more relevant and accessible.

As an NGO in official relations with the World Health Organization, GSCF contributes to WHO's public health goals through its specialised expertise in self-care and responsible self-medication. GSCF is working with WHO in a number of areas to address the overarching strategic priorities of achieving Universal Health Coverage and promoting healthier populations.



The CHP Australia Board

BOARD OF DIRECTORS



Theresa Agnew GlaxoSmithKline Consumer Healthcare (ceased August 2019)



new Robert Barnes Kline Aspen Australia althcare (Treasurer)



Jonathan Biddle Care Pharmaceuticals (from April 2019)



Glenn Cochran RB



Doug Cunningham Johnson & Johnson Pacific (Vice-Chair) (ceased February 2019)



Lindsay Forrest Consultant (Chair)



Andrew Jenkin Pfizer Consumer Healthcare



James Jones (Secretary)



Alan Oppenheim Ego Pharmaceuticals



Mark Sargent Bayer Australia



Seona Wallace HealthOne

CHP AUSTRALIA BOARD COMPOSITION

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

The CHP Australia Board consists of up to ten Directors as follows:

- Up to six Directors elected from the Official Delegates of the CHP Australia 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, CHP Australia 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 CHP Australia Elected Directors as at 30 June 2019:

- Theresa Agnew, GlaxoSmithKline
 Consumer Healthcare
- Robert Barnes, Aspen Australia (Treasurer)
- · Jonathan Biddle, Care Pharmaceuticals
- Andrew Jenkin, Pfizer Consumer Healthcare
- Alan Oppenheim, Ego Pharmaceuticals
- Mark Sargent, Bayer Australia.

The CHP Australia Skills-based Directors as at 30 June 2019:

- Glenn Cochran, RB
- Lindsay Forrest, Consultant (Chair)
- James Jones, (Secretary)
- Seona Wallace, HealthOne

CHP Australia Members

Current at time of printing.

ORDINARY MEMBERS

Allergan Australia Pty Ltd Apotex Pty Ltd Aspen Pharmacare Baxter Laboratories Bayer Healthcare Consumer Care Biocellular Australia Pty Ltd Care Pharmaceuticals Pty Ltd Church & Dwight Australia Combe Asia Pacific Pty Ltd Ego Pharmaceuticals Pty Ltd Endeavour Consumer Health Ensign Laboratories Pty Ltd GSK iNova Pharmaceutical Australia Pty Ltd HealthOne Pty Ltd H W Woods Pty Limited Johnson & Johnson Pacific Pty Ltd Nestle Australia Ltd Pfizer PFE Australia PTY Ltd RB Sanofi Aventis Healthcare Pty Ltd Takeda Pharmaceuticals Australia Tismor Health & Wellness

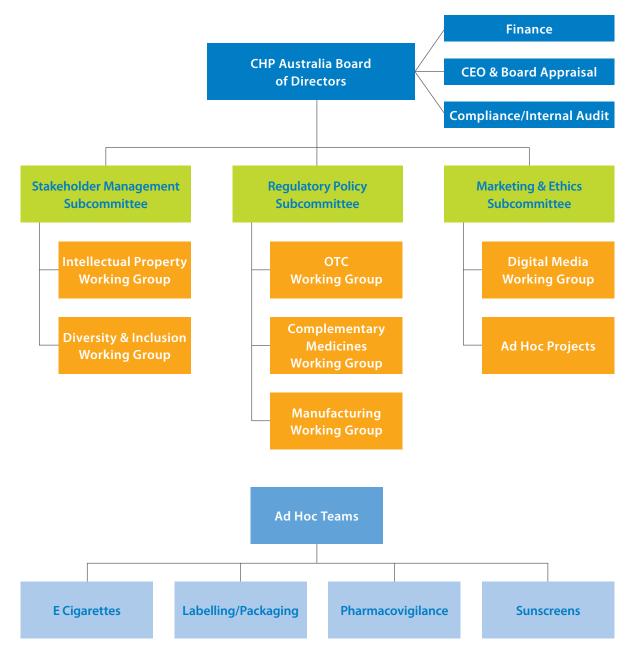
ASSOCIATE MEMBERS

Archer Emery & Associates Avicenna Consulting Australian Pharmaceutical Publishing Co. Pty Ltd (APPco) Brandwood CKC Cube Eurofins Dermatest Pty Ltd Engel, Hellyer & Partners Pty Ltd iLearning Group IQVIA Australia Pty Ltd IRI Australia Pty Ltd Lipa Pharmaceuticals Ltd Natalie Gauld Ltd Nexus APAC Group Pathway International Pty Ltd Purvis Regulatory Consulting Pty Ltd Scientific & Regulatory Solutions Semcom Visual Communication Sue Akeroyd & Associates TVSN Vitex Pharmaceuticals Xena Technologies Xpotential Australia & NZ

Sub-committees & Working Groups

CHP Australia has several sub-committees and working groups that meet regularly throughout the year to work on specific projects and issues that arise. This gives members the opportunity to:

- Contribute to the CHP Australia position on key issues
- Shape industry work
- Keep up to date with current issues
- Meet with the TGA.

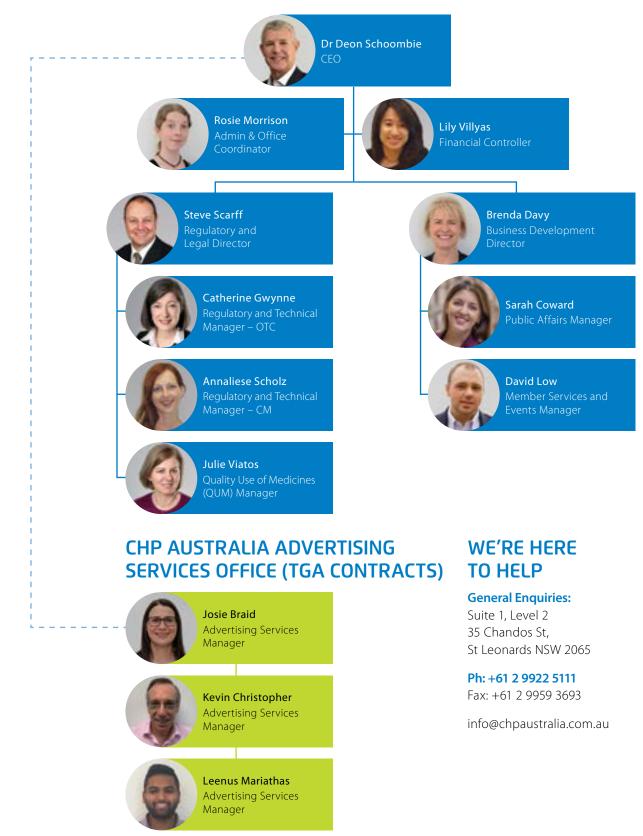


CHP Australia 2018–19 Annual Report 1

CHP Australia – Your Support Team

CHP AUSTRALIA SECRETARIAT

Current at time of printing.



CHP Australia – Your Support Team

CHP AUSTRALIA 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 CHP Australia 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

- CHP Australia Code
- CHP Australia Complaints Panel



Member Events

- World Class Annual Industry Events
- Round table dinner/breakfasts
- Education Seminars
- Members Forums/Meet the CHP Australia board
- Parliamentary events
- CHP Australia Diamond Awards for Excellence in Marketing & Sales



Member Training

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





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