

Annual Report 2014 - 2015



cma Complementary
Medicines
Australia

ABN: 49 169 036 088

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From the President

Complementary Medicines Australia is now well placed to deliver the political and regulatory agenda that the industry has been campaigning and championing for over a decade. We have an excellent Board of Directors in place, representing the whole supply chain. Together with the fantastic team at the Association led by our CEO Carl Gibson, I am confident for the future of the industry.



This is my last report as your President, as I step down at the Annual General Meeting, after over four years in the role.

We have seen tremendous change in the industry over that period and I truly believe that we have matured into a professional industry focused on delivering quality products that support the preventive healthcare agenda.

The outlook for the industry is incredibly healthy.

Our strong partnership with AusTrade, together with our Export Taskforce has helped open up new markets for our industry. Exports are booming, over the last two years we have seen exports of Australian complementary medicines grow 36% and in the last year alone Exports to Asia more than doubled.

The Quality Taskforce under Ian Chant's leadership have developed a Quality improvement process which will help ensure that we maintain our focus on manufacturing and delivering products that are the

envy of the world. They also held a Seminar focussed on driving and promoting Quality in our industry.

The Deregulation Taskforce led by Justin Howden has been instrumental in developing and delivering our 'Light-Touch Right Touch' message to the key decision makers – and we are already starting to see the benefits of their advocacy.

Last year we held six events including our successful Annual Conference and Industry Awards. My thanks to the Marketing and Communications Committee led by Kerry Cunningham for developing these great industry leading events that help share industry knowledge and best practice.

I am also pleased to report a record number of new members joining the Association. Last year we welcomed 18 new members, and my thanks to Natasha Flynn and the Membership Committee for all their work in ensuring we have a vibrant Association fit for the future.

Around 50% of the work of the Association is focused on Regulatory issues. I am truly grateful for the hard work and contribution made by all Companies involved in the work of the Regulatory & Policy Committee, led by Paul Mannion,

Without your diligence and focus on the detail we wouldn't have one of the world's leading regulatory regimes ensuring Australian products are the highest quality in the world.



Our Political Committee, led Mark Bisset, has helped shape and influence the future. Our Association is highly respected across all the main political parties and we have a strong and respected voice on the Hill in Canberra. Our Political reception was the best yet, offering our Members the opportunity to mix and mingle with the key decision makers in Canberra.

The Board of Directors would also like to record their thanks to Michial Coldwell who will be retiring as a director following the AGM.

I am pleased to report that as I leave the role of President, the association is in a stronger position. We have returned to profit and my thanks to the Finance & Audit Committee led by John Baker for all their hard work in ensuring that Members funds are used to the maximum benefit and that our finances are strong for the future.

Finally, my thanks to you our Members for all your years of support and friendship and to my fellow Board of Directors for their vision, energy and dedication to make sure we grow stronger as the industry advocacy body.



Richard Henfrey - CMA President



From the Chief Executive Officer

Lots Done – Lots to Do

They say a week is a long time in Politics...so you can imagine how much has changed in the last year for our industry.

Last year, I reported that we had launched our 'Light-Touch, Right-Touch' Deregulation agenda, outlining a series of reforms that would generate a saving of \$70 million per annum for our industry.

This year I am pleased to report excellent progress in delivering against our agenda.

The Government established an independent expert panel to review the regulatory framework for complementary medicines. We have already seen a record number of new ingredients approved by our regulator the Therapeutic Goods Administration (TGA), with more to be approved soon.

The TGA has established a working group to look at tackling manufacturing complexity, and changes have already started to happen.

Our advertising pre-approvals service has also been transformed with a number of reforms implemented, leading to the majority of adverts being approved in days not weeks.

Our new brand Complementary Medicines Australia has resonated well with our key stakeholders, Government and the media – and has helped give us a sharper, focused and more positive image for the industry.

We have shifted media perception, with over 15 journal features and 50 positive mentions – analysis shows we secured a 60% positive media share for our industry.

The Association ran a number of successful events

during the year including a Political Reception in Canberra, The Quality Seminar, Export Master Class, Compliance Seminars and our very popular Annual Conference and Industry Awards – my thanks to everyone who attended, those nominated and congratulations to all our winners.

We also pioneered new ideas with a Member Roadshow, and the innovation of webinars with our partners at AusTrade to help open up new overseas markets for our members.

Our education program has also been refreshed, thanks to the help of our friends at Endeavour College. Our Introductory Certificate and Diploma are now online, interactive and engaging and a fantastic industry resource.

I would personally like to thank all our Members for their continued loyalty and support – I am so proud to be able to represent our industry.

A big thank you to the whole team at Complementary Medicines Australia who quietly and confidently deliver against our work program, which helps us meet our strategic objectives.

I would also like to thank our Board of Directors for their encouragement and industry knowledge – they play a vital role in setting our strategic direction.

And a personal thank you to our President and my friend, Richard Henfrey for his outstanding contribution at the helm of the organization for over 4 years, our association and industry has thrived under his leadership.



Carl Gibson - CMA CEO

A handwritten signature in black ink that reads "Carl Gibson". The signature is fluid and cursive, matching the name of the person in the portrait above.





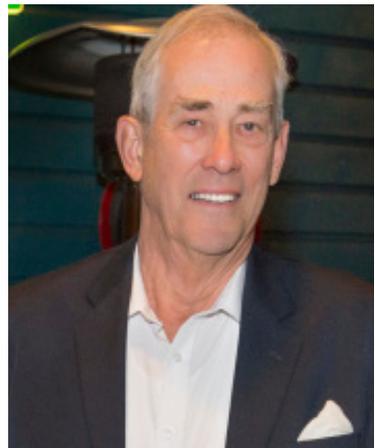
Treasurers Report

The aim of Complementary Medicines Australia is to drive forward the industry’s agenda and advocate for a positive political and regulatory agenda that encourages and supports preventive healthcare.

Our primary goal is not to make a profit – but to make sure that member funds are used effectively to meet our objectives. Having said that, we also have a duty to members to make sure your Association is financially solvent.

I am pleased to report in the last year that we have seen a turn-around in our fortunes. We entered the year with a deficit of \$53,565 and at the end of this year I can report a credit surplus of \$51,658, restoring total members funds to \$400,000.

The change in leadership in the Association is having a positive effect on not just the political and regulatory environment, but also on the finances of the organisation. Advertising pre-approvals has been transformed from a loss making service to break-even. Interest from new members and a series of successful events also give us renewed confidence for the future. My thanks to Carl, Carol, Philip and the whole team who strive to ensure that we have a strong thriving Association.



John Baker - CMA Treasurer



CMA Board



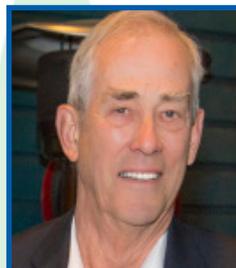
Richard Henfrey

President
Blackmores
Chief Operating Officer



Dusko Pejnovic

Vice President
Lipa Pharmaceuticals
Chief Executive Officer



John Baker

Treasurer
Go Vita Springwood
Owner / Manager



Ian Chant

TSI Pharmaceuticals
Managing Director



Paul Mannion

Health World
Technical Director



Sally Brumley

Queanbeyan Mega Health
& Leura Health Foods
Owner



Wayne Coote

Pathway International
Managing Director



Carolyn Barker AM

Endeavour Learning Group
Chief Executive Officer



Mark Bisset

Catalent Australia
General Manager Australia/Asia



Natasha Flynn

Caruso's Natural health
Business Development & Naturopathic Manager



Kerry Cunningham

Blackmores
Director of Retail Operations



Justin Howden

Swisse
Head of Government Relations, Public Policy
Appointed September 2014



Michial Coldwell

Amway of Australia and New Zealand
General Manager



CMA Secretariat



Carl Gibson
Chief Executive Officer



Emma Burchell
Head of Regulatory Affairs



Karen Hocking
Head of Government Relations
& Industry Development



Carol Hart
Head of Finance



Dee Watson
Business Manager



Philip Anderson
IT Manager



Miho Kikuchi
Industry Development



Alice Callahan
Communication, Marketing and
Events



Chelsea van Zyl
Business Development

CHC Office of Advertising Compliance



Tricia Campbell
Advertising Compliance
Manager



Ruben Jones
Advertising Compliance
Manager



Kirili Anderson
Advertising Compliance
Manager

Staff not pictured: Tony Lewis Advertising Services Manager



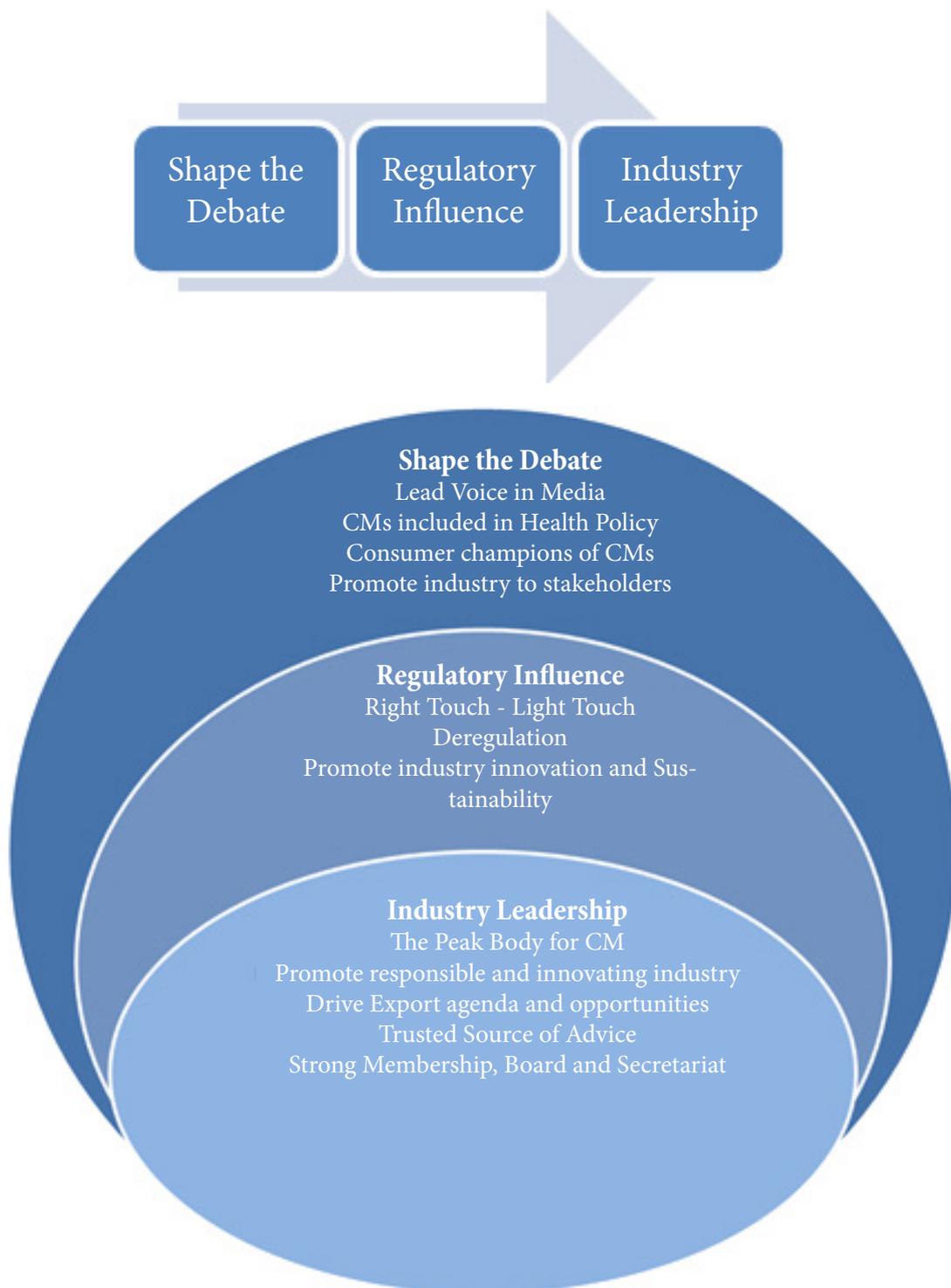
CMA Vision

The Voice of the Complementary Medicines Australia

Complementary Medicines Australia is the only peak industry body that represents the whole of the Complementary Medicines in Australia.

CMA is devoted to improving the health of the community through advocacy for sustainable health and wellbeing.

CMA Strategic Plan



Regulatory Affairs

CMA has implemented a renewed strategic focus over this reporting period. We continue to build on our regulatory engagement and key relationships within the Therapeutic Goods Administration and other government departments with a strong focus to influence an appropriate light touch, right touch regulatory framework for complementary medicines in Australia.



In shaping the national complementary medicines agenda, CMA strives to influence an appropriate and simplified regulatory regime - one that is supportive of innovation and competitiveness and builds on the robust safety and quality standards for Australian complementary medicines.

In response to the Australian Governments Deregulation Agenda, CMA saw an opportunity to put forward its' vision of an appropriate regulatory model. We continue to work collaboratively with the regulators to ensure industry leadership through policy development, research, and advocating other possible improvements that will lighten the regulatory load of the Australian complementary medicines industry.

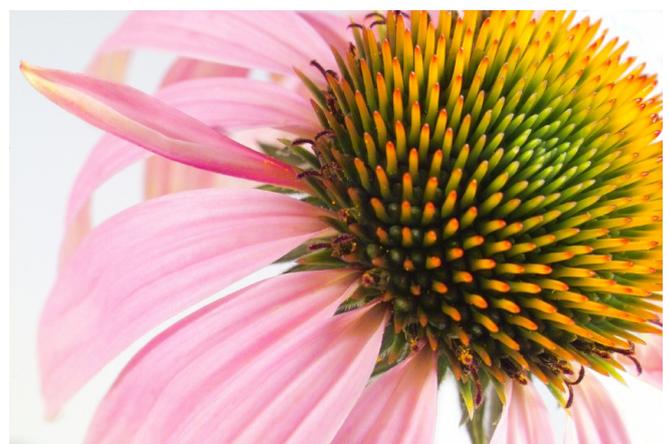
CMA, under its deregulation agenda is, like the Government, committed to see a reduction in

the cost of unnecessary or inefficient regulation. CMA supports that the package of reforms to complementary medicines be refined such that they minimise regulatory burden and impact on a compliant industry while offering a framework for high quality complementary medicines to be made available in a timely manner to informed consumers.

Complementary Medicines Business Process Review:

CMA members are actively involved in the TGA-Industry working group for the Business Process Review (BPR) to Complementary Medicines. Such a project provides an opportunity to expand on concepts outlined in CMA's deregulation agenda and to gain efficiencies in the market authorisation process for registered complementary medicines and new substance applications.

The BPR project ultimately aims to streamline applications according to a risk based regulatory approach and apply risk-appropriate evaluation processes. A review to the business processes of the TGA is set to provide industry participants with greater transparency and predictability of the regulatory processes and provide a more efficient and cost effective evaluation process.



Permitted Indications for Listed Medicines :

While the proposed legislative amendments associated with the permitted indications reform have been put on hold pending broader consideration of the



governments deregulation agenda, members have actively been responding to aspects of the reform that can be implemented within the existing framework. To this end, focus has turned to a list of priority indications that may refer to restricted representations, the use of which requires prior approval under the Therapeutic Goods Act 1989. CMA successfully submitted to the TGA an application for a group approval to use a range of restricted representations in listed medicine advertising.

New Zealand Natural Health and Supplementary Products Bill:

The NZ environment of regulatory change continues to see the progression of the Natural Health Products Bill through the NZ Parliament. As the Australian complementary medicines industry proceeds with its own set of reforms, outside of the previously proposed ANZTPA, CMA will be keeping a close watch on how natural health products will be regulated across the ditch.

International Standard Setting:

CMA provides a volunteer representative on the Standards Australia Technical Committee for Traditional Chinese Medicine within the International Organisation for Standardization (ISO) TC 249. This work takes place via the Standards Australia mirror committee HE-031, including its sub committees on the quality and safety of TCM manufactured products and raw materials.

Standards Australia recognise CMA as an important and strategic participant and contributor in providing national guidance in the field of standardization and this facilitates early visibility on international Standards development activities and initiatives. Since its inception, the Australian Committee has voted on draft international standards as they have been developing and has been instrumental in drafting resolutions, contributing to the success of meetings. This committee, ISO/TC249, has published its first two international standards:

ISO 17217-1:2014 -Traditional Chinese medicine - Ginseng seeds and seedlings Part 1: Panax ginseng C.A Meyer and ISO 17218:2014 - Sterile acupuncture needles for single use.

Industry Engagement – Regulatory & Technical Committees:

CMA fosters a sense of belonging and passion amongst members by facilitating access to collaborative decision-making on regulatory standards and policy issues through a range of committees and working groups. The work of these experienced committee members is essential in CMA providing leadership in its regulatory and advocacy endeavours.

CMA wishes to acknowledge and extend its appreciation to all committee and working group members for their dedication and hard work on behalf of industry.

Future Regulatory Directions:

The CMA Secretariat is set for an engaging 2016, one that will see the implementation of recommendations from the independent review of medicines regulations for complementary medicines. Through the representation of our members, collaboration with regulators and industry stakeholders, we will continue to progress a positive, light touch - right touch regulatory framework for complementary medicines.

By developing submissions, industry agreed positions, and being proactive on relevant CM issues, the work of CMA on behalf of industry will continue to be productive and results driven.



CMA Submissions 2014-2015

2015

- Submission to IP Australia - Innovation Patent System (28 September 2015)
- Submission to TGA - draft revisions of Chapters 1, 2, 6 & 7 of the PIC/S GMP Guide (2 September 2015)
- Submission to Ministry of Health - NZ Natural Health Products Bill - Supplementary Order Paper (27 August 2015)
- Submission to TGA - New ingredients proposed for expedited approval (28 July 2015)
- Submission to Department of Industry and Science - Australian Consumer Law: Possible Changes to Country of Origin Safe Harbour Defences (Thursday, 2 July 2015)
- Submission to the Department of Health - Reducing Regulation in the Health Portfolio (June 2015)
- Submission to TGA - Update to the Uniform Recall Procedure for Therapeutic Goods (May 2015)
- Submission to TGA - Adoption of European Union (EU) scientific guidelines for herbal medicines (17 April 2015)
- Submission to the Expert Review of Medicines and Medical Devices Regulations (8 April 2015)
- Submission to TGA - Evidence guidelines checklists (2 March 2015)
- Submission to TGA - Proposed new annual charges exemption scheme (4 February 2015)
- CMA 2015/16 Federal Pre-Budget Submission (January 2015)

2014

- Submission to Expert Panel - Review of Medicines and Medical Devices Regulation Secretariat Department of Health (23 December 2014)
- Submission to the TGA on the priority list of Permitted Indications (10 October 2014)
- Submission to Queensland Department of Health:

Consultation Draft Medicines, Poisons and Therapeutic Goods (3 October 2014)

- Submission to TGA - Updated material on section 14 and 14A consents (2 September 2014)
- CMA transcript submission - Public hearing of the NSW Health Care Complaints Commission - Inquiry into the Promotion of False or Misleading Health-Related Information or Practices (10 September 2014)
- CMA submission to DFAT - Free Trade Agreement between Australia and China (11 September 2014)
- CMA application to TGA for a group approval to use a restricted representation in advertising (26 September 2014)
- CMA submission to FSANZ - Proposal P1030 Health claims - Formulated supplementary sports foods and electrolyte drinks (30 September 2014)
- CMA request to the NHMRC under FOI for documents in relation to the Homeopathy Review (August & September 2014)
- Submission to NHMRC Faculty Steering Group - Case for Action (August 2014)
- Submission to the Senate Standing Committee on Economics - Inquiry into Australia's Innovation System (August 2014)
- Submission to TGA - Section 14/14A form and guidance document (11 August 2014)
- Submission to TGA - ARGCM Part D: Registered Complementary Medicines (12 August 2014)
- Submission to TGA - Evidence required to support indications for listed medicines – Journal Impact Factors (21 August 2014) Submission to the Senate Standing Committee - Economic Inquiry into Australia's Innovation System (27 August 2014)
- Submission to TGA Manufacturing Quality Branch – Scenario for Release for Supply Guidance Part 2 (22 July 2014)
- CMA proposal for a National Registration and Accreditation Scheme for Complementary and Alternative Healthcare Practitioners (1 July 2014)



Advertising Compliance & Complaints Resolution

Edition Two of the Marketing Code (CHC Marketing Code of Practice: Complementary Medicines & Health Food Products) was published in September 2013 following several rounds of consultation with CHC committees, members and external stakeholders. The Marketing Code was revised to be aligned with other key therapeutic industry codes of conduct, which are all now based on a common set of high level principles.

The Complaints Resolution & Monitoring Committee (CRMC) is established under the Marketing Code to manage the co-regulatory system for the marketing of complementary medicines to consumers and healthcare professionals, including:

- below the line advertisements to the general public, including retailers;
- advertisements to healthcare professionals;
- complaints from Government, Industry, consumers and other bodies; and
- taking appropriate action to remedy the situation.

We thank all Complaints Resolution & Monitoring Committee members and commend them for their dedication.

	14/15	13/14	12/13	11/12	10/11	09/10
No. Complaints received	22	15	16	25	31	33
CMA Member / Non Member	4/18	4 11	5 11	4 21	4 27	5 28
Finalised ¹	24	14	24	35	35	41
Forwarded to TGA ³	7	4	7	5	7	6
Referred to CRP	1	2	1	4	9	9

Notes:

- 1 Totals reflect that some finalized complaints were from the previous reporting period.
- 2 Number of companies against which more than one complaint was received.
- 3 Where a complaint received involves risk to public safety or the therapeutic good has not been included in the Australian Register of Therapeutic Goods (ARTG).



NATIONAL CONFERENCE 2014

The 2014 National Conference was a record breaking sell out event, hosting over 150 delegates. The volume and high standard of speakers, exhibitors, delegates and sponsors at the event made it a fantastic networking and educational opportunity for all those in attendance.



The new one day format paved the way for a refreshed and energized conference program filled with engaging speakers. The shorter day allowed CMA to select the very best from a diverse range of speakers with a clear focus on our theme “*The Wellness Revolution*”. The delegate evaluations confirmed this sentiment with some of our highest total speaker satisfaction scores yet!

The conference hosted 9 exhibitors; along with an espresso coffee cart thanks to our major sponsors Aker BioMarine.



As part of the exhibitor passport promotion a range of prizes were handed out, including a FitBit and accommodation package at the Park Royal.

15th ANNUAL INDUSTRY AWARDS DINNER

The award winners shone in keeping with the dinner theme “*All That Glitters*”. With over 260 guests in attendance the night was fun filled and as always a fantastic networking opportunity. CMA welcomed Hayley Lewis – Olympic gold medallist as MC for the formal proceedings along with CMA CEO Carl Gibson and President Richard Henfrey.



To top off the evening the awards dinner sponsor Ferngrove Pharmaceuticals surprised guests with 20 UE Boom Bluetooth speakers to give away as part of a business card lucky draw.

INDUSTRY AWARDS WINNERS 2014

Lady Cilento

Professor Alan Bensoussan – National Institute of Complementary Medicine

Vince Russell Retailer of the Year

Mr Vitamins – Abraham James

High Quality Manufacturer of the Year

Lipa Pharmaceuticals

Most Outstanding Industry Contributor of the Year

The Blackmores Advisory Service Team (Lead by Julie-Anne Atkinson)

Salesperson of the Year

Sue Rennie, Ferngrove Pharmaceuticals



Most Outstanding Contribution to Research, Education or Training

The BioConcepts Education Centre

Quality Raw Material Supplier of the Year

Network Nutrition – IMCD

Wholesaler or Distributor of the Year

Complementary Medicines Group

Most Outstanding Marketing Campaign

Swisse Wellness – The Swisse Colour Run

QUALITY LEARNING SEMINAR

The Quality Learning Seminar was held at the Swissotel, Sydney on the 3rd of June, 2015. This seminar was a first for CMA, attended by 70 members and industry representatives who shared overwhelmingly positive feedback on the event.



CMA was pleased to present an exceptional line-up of speakers, including representatives from the Australian Customs and Border Patrol and from the Therapeutic Goods Administration (TGA). Delegates had the opportunity to speak directly with all the government officials which provoked plenty of insightful and informative conversation.

EXPORT READINESS WORKSHOP

Together with the Export Council of Australia (ECA), CMA hosted the Export Readiness Workshop on the 23 June 2015 in Sydney which was attended by 12 industry representatives.

Peter Mace from ECA delivered the majority of the content and Jim Harrowell from Hunt & Hunt Lawyers presented a section on IP protection. The program highlighted the opportunity for the complementary medicines industry to consider business growth through export and to clarify the process of how to go about it.

CMA MEMBERS NETWORKING EVENT



CMA hosted a fun and valuable networking opportunity for members on the 23rd of July 2015 at the Argyle Complex in the Sydney CBD.

Industry colleagues were provided an opportunity to catch up and attendee feedback confirmed that many new business connections were made at this fun and relaxed cocktail event which was exclusive to CMA members.





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