

Annual Report 2012



chc

Complementary
Healthcare Council
of Australia

Under the spotlight



Richard Henfrey

Australia's population is embracing preventive health measures, with over 75 percent of us now using complementary medicines. Our Industry is becoming increasingly significant, in terms both of our economic impact and our contribution to improving population health outcomes.

The domestic market for complementary medicines is estimated to be worth nearly \$2 billion and the industry employs over 60,000 people. A large part of this achievement is explained by our success in producing innovative high-quality products.

However, our industry is coming increasingly under the spotlight of regulators, government and consumer groups. Industry regulations, which already provide a global benchmark, are currently facing swathes of reform. There is pressure to move towards a regulatory framework more suited to the pharmaceutical industry, yet this would be in an environment that provides little to protect investment in innovation.

However, so long as we speak with a strong and unified industry voice, we have the strategies in place to work together with the key stakeholders to promote industry innovation and consumer choice, resulting in a better Australian health industry.

In the past two years we have engaged well with key stakeholders, promoting who we are as an organisation, why our industry is important and why they should care about us.

In 2012 we have been clear and forthright about what we want as an industry. Key communication vehicles for this have been established with the launch of our business to business magazine *Complementary Medicines Today*, and our consumer print and online magazine *Naturally Australia*.

Also this year, for the first time, we have contributed a submission to the federal government's budget process. The key pillars of our budget submission are the development of an industry plan for the complementary medicines industry, the establishment of a research partnership between industry and government to encourage more clinical trials, and some great ideas around the investigation and commercialisation of Indigenous traditional medicine.

With the likelihood of high levels of regulatory change over the coming years, the CHC is already closely engaged with the team inside the TGA that is developing its implementation plan. This is a vital and ongoing stream of work. We will continue to represent and protect the interests of all our members during this next phase of development.

With a strong platform to support us, we look forward to working with you over the coming year to create a better Australian health system.

Richard Henfrey is President of the CHC Board and Director of Strategic Sourcing at Blackmores

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An industry that matters

The Complementary Healthcare Council is pleased to present its annual report in the following pages of this issue of *Complementary Medicines Today*. If you would like to access a copy online, the CHC's annual report for this and previous years are available to download at www.chc.org.au/Annual-Reports. We realise that not everyone wants to plough through a long and often technical report to find what they want to learn about an organisation and its activities. We therefore hope the following pages will fulfil this need in a more accessible manner, and impress the reader with what the CHC and its valued members have achieved in building the profile of the industry and furthering its agenda.

What you'll find here

We are a significant industry

A concise presentation of key industry facts and figures can be found on page 82, along with a summary of the main challenges facing the industry now and in the near future. It shows that the CM industry is a substantial contributor to the Australian economy and our national preventative health policy, but is not always accorded the recognition in official circles that this hard-earned status warrants.

We have the right people

In her report on page 83, CHC executive director Wendy Morrow covers the regulatory challenges the council has faced and how it has responded. She praises the many dedicated and committed members, particularly those who work so tirelessly on the CHC board and its various committees to further the industry agenda, as well as the council secretariat for their skill, diligence and responsiveness.

Treasurer John Baker explains on page 84 that although the council experienced a more than \$300,000 loss in 2011-12, its financial position remains healthy and viable – this is referring to last year's Financial report. See below.

Those who contribute so ably to the CHC and its objectives as board or staff members are listed at pages 84-85. Also listed on page 85 are a selection of the external committees and working groups in which the CHC participates, and its own internal committees and other groups.

We know what we're doing

The heart of the annual report – a broad summary of its challenges, activities and achievements – is on pages 86-89. The council has expanded its influence through a comprehensive political and community engagement program, and has also adopted an industry-focused policy outreach program with other industry groups.

The CHC has undertaken significant strategic research aimed at profile-building and community engagement, as well as econometric research to investigate the economic benefits of the preventive use of fish oils.

Engagement with members is achieved through an extensive communication program of both a generalist and technical nature. The CHC's and the industry's profiles have been raised to a new level through a sophisticated media strategy that has seen extensive coverage in both mainstream and specialist media.

This is complemented by the launch of both consumer and business-to-business magazines: *Naturally Australia* and *Complementary Medicines Today* (this publication) respectively.

Educational seminars and events round out the stakeholder engagement program. These include the national conference, parliamentary reception and a series of specialist seminars – all well-attended and highly successful.

We're knuckling down to the job

The CHC supports appropriate regulatory reform that aims to increase efficiencies in the industry. To this end the council has lobbied hard with the Therapeutic Goods Administration on a range of technical and regulatory matters in response to the TGA blueprint report, which itself encompassed more than 60 recommendations from reviews, including the Australian National Audit Office performance audit review, the transparency review, advertising reforms, the promotion of therapeutic products working group and the informal group examining complementary medicines regulation. It also provided a comprehensive submission to the consultation on the evidence required to support indications and claims for listed medicines. The regulatory team facilitates members' access to collaborative decision-making on regulatory and standards issues through working groups and committees. These activities are detailed on page 90.

The council continues to develop, monitor, consult on and where necessary update its various codes of practice, including the code of practice for the marketing of complementary medicines and health food products, the complementary medicines retailer's code of practice, the guideline for the sale and supply of practitioner-only products, the guideline for the quality and safety of raw materials used in complementary medicines and the code of practice for the marketing of complementary healthcare and health food products. More details are provided at pages 91-92.

Over 2011-12 the CHC lodged a substantial number of detailed submissions on industry-related matters to several government authorities, including the Therapeutic Goods Administration, Food Standards Australia New Zealand, the Department of Industry, Innovation, Science, Research and Tertiary Education, the National Health and Medical Research Council, the Department of Agriculture, Fisheries and Forestry, the federal government (the first ever CHC pre-budget submission) and the NSW government (on the manufacturing industry action plan as it related to complementary medicines). These submissions, all of which can be accessed via the CHC website, are listed on page 93.

The CHC's strength is in its members. The ways in which members are engaged, and the services and advantages members enjoy, are detailed at page 94.

Finally, as explained on pages 94-95, the CHC takes its education and professional development responsibilities seriously. Its expanding suite of accessible certificate and diploma courses are complemented by an impressive program of seminars and conferences organised around themes of more immediate industry interest and concern. The council also recognises its responsibility to communicate openly and directly with industry and consumers, which is achieved through a variety of media, not least this publication.

Snapshot of Australia's growing complementary medicines industry

Complementary medicines is one of Australia's most successful and innovative industries, with major contributions to employment, exports and research and development.

There are 254 CM companies in Australia generating around \$2 billion in annual revenues. The industry provides around 5000 highly skilled manufacturing jobs at a time when the future of Australian manufacturing is clouded, and indirectly supports a further 60,000 jobs.

Production of CMs in Australia is a substantial industry, with 59 TGA-approved manufacturing facilities throughout Australia.

Industry revenue is estimated at about \$2.3 billion annually. Australian companies export around \$200 million in CMs to more than 20 countries in South-east Asia, Europe and the Americas. Exports continue to grow at a higher rate than domestic consumption.

Industry issues

Over the past few decades, the sector has evolved from something of a "cottage industry" to a major industry subject to a tight regulatory regime, which requires complex supply chains, clinical trials, global marketing and export acumen. While this transformation is unambiguously positive, it has brought with it a set of policy issues which need to be addressed if the industry is to continue to employ highly skilled manufacturing workers and maintain export momentum.

The CM industry shares with manufacturing generally the challenge of a high Australian dollar and competitive challenges from overseas producers. Consumers in other countries are turning to CMs manufactured in Australia because of our solid, hard-won reputation for quality and for high manufacturing and safety standards. The industry is seen as clean, green and competitive, and recognises that its future lies in competing openly in global markets on the strength of our world-class products. It is not seeking a return to tariffs or other forms of industry protection, although there is certainly scope for introducing imaginative industry programs to support innovation and skills development.

There are also challenges peculiar to the CM industry. The first is a lack of recognition of the need for intellectual property protection – an issue not faced by a pharmaceutical manufacturer, which needs only patent a new chemical entity. But at present anyone can with near impunity copy a formulation that is a combination of herbs once they know the recipe – a huge disincentive to investing in research.

The second relates to regulatory reform. While the industry respects the importance of a robust regulatory regime for CMs and the competitive advantage it gives our industry in export markets, it is also concerned that it may end up with a regulatory regime where CMs are assessed against medical criteria similar to those applying to the pharmaceutical industry, resulting in unnecessarily complex and unclear regulations that place an unwarranted burden on businesses and reduce industry competitiveness. The CHC will continue to press through all appropriate forums for levels of regulation appropriate to both industry and consumer needs.

More generally, the CHC urges governments and health authorities to acknowledge the role that CMs play in preventative health by, for example, including CMs in a revised operational plan for the new Australian National Preventive Health Agency (ANPHA), which currently fails to mention them. This would provide the impetus for an ANPHA-funded research project into the preventive health benefits of CMs. The NHMRC too offers negligible funding support for research into CMs.



Focusing on our strategic priorities

Wendy Morrow

It's been an exciting and challenging year for the CHC and our industry. In line with the political climate and changes to be brought on by a Australian National Audit Office report, we have focused on influencing the regulatory agenda. The relationship-building and lobbying have reflected a revitalised and proactive drive to progress our reform agenda.

Providing leadership to the industry

With the outcomes of five major government reviews being distilled into a TGA blueprint on 8 December, the Parliamentary Secretary for Health and Ageing, Catherine King, announced her plans to reform the TGA 2011. The CHC has played a strong leadership role in discussions on these reforms, and our key achievements to date include the rethinking by the TGA on the levels of evidence consultation.

Being the voice of the industry

The CHC is well poised to capitalise on the increasing focus on our industry through an ever-expanding presence. The current volatile political and regulatory environment means that the CHC must act positively. Stakeholder engagement is a priority for the CHC. A main focus has been the identification and fostering of relationships with key organisations and relevant personnel to ensure that we are included in the critical decision-making processes affecting complementary medicines.

Focused political initiatives, leveraging of the industry audit and a proactive media strategy are enabling us to shape the agenda. The CHC has developed, and will continue to develop, industry positions on identified priorities, and will continue to disseminate vital information.

Strong and vital membership base

The complementary medicine and healthcare product industry is a broad and diverse one. Several sectors, each with their own needs and challenges, require a flexible and fast-moving secretariat. As the CHC is the peak industry association, it represents participants at all levels of the value chain involved in complementary medicines, including raw material wholesalers and distributors, manufacturers, marketers, retailers and, increasingly, consumers.

The term complementary medicine refers to vitamin, mineral, herbal and other nutritional supplements and natural health products. We conducted consumer research that suggests that more than 70 percent of Australians consume complementary medicines every year. Given the role that complementary medicines are already playing in the healthcare of so many Australians, it would be appropriate for our industry to have more of a voice when it comes to setting health policy for our nation.

This past year, we have focused our efforts on the importance of our industry beyond matters of health policy. We published an industry audit that showed that this industry directly employs 5000 people, exports

\$200m and generates around \$200m of GST revenue. We are able to demonstrate how these numbers break down by state, and particularly the contribution to economic growth made in the less resource-rich states of NSW and Victoria.

The role of the CHC committees and working groups (highlighted later in this annual report) are crucial to ensuring industry opinions are canvassed. I ask that all members consider both active involvement in the committees and requests for comments.

I cannot say thank you loud enough to our tireless committee and working group members for your invaluable assistance in crafting industry positions on critical issues and your willingness to assist the CHC to achieve its goals.

We wish to also convey our thanks to the hard-working CHC secretariat. Without their efforts the many tasks required of us would not get done. In a small office such as ours, staff are often required to leave their own work to assist others and undertake tasks that were never envisaged as part of their job description. Our people are always ready to help out. Without their commitment, their flexibility and their expertise, we simply could not get through the volume and complexity of work that we have to in order to support this great industry.

Thank you for joining with us to help achieve improved health and wellbeing outcomes for all Australians.

Wendy Morrow is executive director of the CHC.

Treasurer's Report

At the time of going to press the CHC audit has not been completed, however, I am confident that we have achieved what we undertook to do 12 months ago, which was to fulfil our programme of services and return a positive financial outcome.

I am very pleased to report a profit of \$21,421 for the financial year ended 30th June 2012. This increases accumulated members funds to \$382,3383. Overall income increased by 6.7% although Interest Earned was down, however, Events Income inclusive of Sponsorship, grew by 19% and Member Subscriptions up by 0.5%.

There was also a significant growth in Advertising Approvals the fees for which increased by 39.4%. In addition, overall Expenses were reduced by 12%.

The Board and the Secretariat have worked hard to establish improved financial planning and to significantly strengthen internal controls. Ongoing initiatives continue to include efforts to diversify income streams such as the Education Programme which contributed \$24,000 in the year.

In conclusion I would like to thank Dr. Wendy Morrow for delivering a positive outcome. Additional thanks go to our Accounting and Administration team, Gail Savage and Phil Anderson, our external Accountant, Ben Jennings, and lastly the Board's strengthened Finance and Audit committee, all of whom have worked willingly and well to achieve such a pleasing result.

John Baker, CHC treasurer.

Complementary Healthcare Council board and secretariat

The board



President:
Richard Henfrey
(Blackmores)



Vice-president:
Sally Brumley
(Leura Healthfoods and
Queanbeyan Mega
Health)



Treasurer:
John Baker
(Go Vita Springwood)



Frank Caruso
(Totally Natural
Products)



Wayne Coote
(Pathway International)



Anthony Greig
(Amway of Australia)



Warren Morey
(The Pharmaceutical
Plant Company)



Paul Mannion
(Health World)



Mark Bissett
(Catalent Australia)



Dusko Pejnovic
(Lipa Pharmaceuticals)



Radek Sali
(Swisse)



Vincent Tan
(Pharmacare)



Paul Rose
(Pfizer Consumer
Healthcare)

The secretariat



Dr Wendy Morrow



Phil Anderson



Emma Burchell



Tricia Campbell



Karen Hocking



Katrina Jack



Ruben Jones



Sophie Newsome



Hannah Richmond



Gail Savage



Dee Watson



Justin Howden

Committees and working groups

External Committee Representation

- Australian Quarantine and Inspection Service Biologicals Consultative Group
- Australian Quarantine and Inspection Service ICON Redevelopment Project (BICON)
- Complaints Resolution Panel (CRP)
- FSANZ - Nutrient Reference Values Scoping Study - Workshop
- Healthcare Recall Advisory Council & Reference Group
- International Alliance of Dietary Supplements Association Technical Working Group (IADSA)
- International Alliance of Dietary Supplements Association Adverse Event Reporting Global Guidance document Working Group
- National Institute of Complementary Medicines (NICM)
- National Medicines Policy (NMP) Working Group – Informed and Active Consumer
- National Medicines Policy Partnership Forum (NMPPF)
- Office of Complementary Medicines/Industry Consultation Group (OICG)
- Pharmaceutical Industry Working Group (PIWG)
- TGA Office of Manufacturing Quality – Complementary Medicines Regulatory Reform Informal Working Group (CMRRIWG)
- TGA Therapeutic Goods Order No. 78 Working Group
- TGA Prototype of the Database of Adverse Event Notifications Testing Group
- TGA Informal Working Group on Complementary Medicines (IWGCM)
- TGA Transparency Review Committee
- TGA Over the Counter Business Process Reform (OTC BPR)
- Therapeutic Goods Administrations Industry Consultative Committee (TICC)
- Therapeutic Goods Advertising Code Council (TGACC)
- Therapeutic Goods Committee (TGC) and sub committees
- Completed Advisory Board
- Department of Health and Ageing Working Group on the Promotion of Therapeutic Products

Industry Representation and Conferences

- Australian Broadcasting Corporation Insight Program – Male Body Image
- Australian Pharmacy Professional Conference (APP)
- PSA Clinical Practice Expo (CPEXpo)
- Direct Selling Association of Australia Conference (DSAA)
- Food Medicine Interface Meeting NSW Food Authority
- International Conference on Mechanisms of Action of Nutraceuticals (ICMAN5)
- Medicines Australia Annual Parliamentary Dinner
- Natural Products New Zealand Conference (NPNZ)
- Pharmacy Guild Annual Conference
- MediQ Forum
- “Why policy and politics matter to patients” – The Hon. Nicola Roxon, MP at the National Press Club
- Committee for Economic Development of Australia (CEDA) State of Health, Ministerial Address
- “Where do your medicines come from and why should you care” – Dr Brendan Shaw, Medicines Australia at the National Press Club.
- Swinburne University of Technology Opening of Advanced Technologies Centre
- Pharmacy Guild of Australia Annual Parliamentary Dinner – Address from The Hon Tanya Plibersek, Minister for Health
- Australasian College of Nutritional and Environmental Medicine (ACNEM), Food and Nutritional Sciences Division of the CSIRO, and Nutrition Society of Australia (NSA) 2nd International Conference on the Science of Nutrition in Medicine and Healthcare.
- Federal Budget Dinner
- Trans Tasman Business Circle

CHC Technical Committees and Working Group Meetings

- Advertising Working Group
- AQIS Working Group
- CHC Pharmacovigilance Working Group
- Food/Medicine Interface Working Group
- Homoeopathic Working Group
- Manufacturing & GMP Technical Committee
- Practitioner Medicine Technical Committee
- Raw Material Suppliers Technical Committee
- Regulatory Policy Committee
- Regulatory Technical Committee
- Sports Supplement Industry Group

The year in review

Political and consumer affairs

The strategic focus over the past 12 months has been to build on the profile and position of the CHC and the whole of the industry with industry, government and consumers, drawing on new and existing relationships developed over recent years.

Expanding our sphere of influence

The CHC has succeeded in expanding the reach of our influence through a comprehensive political and community engagement program. With the Department of Health and Ageing the focal point, the CHC engaged more extensively with federal and state departments, state business agencies, food authorities and health agencies through policy briefings, round tables, working groups and committees to cement the industry's position as a science, R&D and manufacturing force with a strong population health outcome focus and a sizeable impact across a range of sectors.

In line with this engagement program and the building of the industry profile, the CHC has continued its industry-focused policy outreach program with industry groups, including the Australian Chamber of Commerce and Industry, Australian Industry Group, Australian Trade Commission (Austrade), American Chamber of Commerce, Committee for Economic Development of Australia (CEDA) and Research Australia.

Key activities and achievements

The engagement program has facilitated a range of activities and initiatives reflecting our strategic focus:

lodgement of the first CHC federal budget submission (February 2012)

federal budget submission follow-up program, briefing relevant ministries and departments

regular briefings with the office of the Parliamentary Secretary for Health and Ageing, Catherine King

formation of a CHC consumer focus group, providing industry with a genuine consumer perspective on industry issues and developments to inform lobbying activities

initiation of dialogue with various groups, including IP Australia, the University of South Australia, the University of Technology Sydney and Aboriginal Bush Traders around Indigenous medicines projects, in line with the CHC budget submission

sound industry positioning and media rebuttal to public assertions from Friends of Science in Medicine (FSM) around the teaching of CM in higher education

recognition from key government stakeholders of industry positioning and impact through the development at TGA urging of updated levels of evidence guidelines.

Groundbreaking research

The CHC has undertaken significant strategic research aimed at profile-building and community engagement. In November 2011, UMR Research was commissioned to explore consumer choice, purchasing behaviour and product labelling. The research outcomes have been vital in promoting informed consumer choice, and will play a central role in future lobbying activities.

The CHC also commissioned Deloitte Access Economics to investigate the economic merits of the preventive use of fish oils. The findings of the report were of significant impact to economic and population health outcomes. Acknowledging the weight of the findings, the report was introduced at the launch of the CHC's B2B magazine, *Complementary Medicines Today*, in February 2012 in the presence of industry and media leaders. Industry associations showed considerable interest in the research, and the report was covered by the Fairfax group in all major city dailies and Sunday editions, as well as through online and radio interviews.



Communicating our message

The CHC has continued to streamline its communications by implementing the council's new look and feel. The council engages with members through a series of targeted communications including the fortnightly CHC The Edge newsletter, newsflashes, retailers' alerts, technical alerts and updates.

Throughout 2011-12 the CHC distributed 29 media releases, 26 The Edge newsletters, 21 member-only newsflashes and 55 technical alerts and updates.

The council has also continued to expand its reach among health-specific and mainstream media. We have confronted industry challenges and voiced industry concerns on issues such as innovation and intellectual property protection, R&D incentives and advertising of CMs, as well as highlighting the significance of the industry to the Australian economy and its impact on population health outcomes. This program has resulted in articles and features appearing in national print and online publications, with the CHC increasingly becoming the first point of contact for media on CM issues.

Did you spot the CHC features?

- *Women's Health* (June 2012)
- *Retail Pharmacy* (December 2011, April 2012)
- *Retail World* (May 2012)
- *The Daily Telegraph*
- *4BC*
- *2UE*
- *Australian Indigenous Health Infonet*
- *National Indigenous Radio Service*
- *The Australian*
- *Sydney Morning Herald*
- *Canberra Times*
- *ABC News Online*
- *Pharma-in-Focus*
- *Pharmacy Daily*
- *Pharmacy News*
- *Postscript Interactive*
- *U on Sunday*
- *Complementary Medicines Today* (Edition 1 and 2)
- *Naturally Australia* (summer and winter)

We have also reacted promptly and effectively to various issues raised in the media, including the teaching of CM courses in higher education, product labelling, consumer choice, levels of evidence and online purchasing of CMs.

Our media activities have been complemented by the launch of the CHC's consumer and B2B magazines, *Naturally Australia* and *Complementary Medicines Today*. *CMT* was launched in February 2012 to around 130 industry and media guests. This magazine, which is targeted at government and industry, includes independently written articles providing readers with the latest information on CMs and industry issues and activities. *Naturally Australia* was introduced to consumers and communities from March 2012 through nationwide launch events and consumer-specific online portals and social media apps. Key events took place at major commuter hubs, and CBD and beach hotspots in capital cities. Over 100,000 copies were distributed through pharmacies, supermarkets, cafes, salons and selected newsstands, reaching a wide cross-section of consumers.

Events

Supplementing our communications and publications is our annual program of events, including the national conference (October 2011), launch of our B2B magazine *Complementary Medicines Today* (CMT) and parliamentary reception (March 2012).

2011 National Conference and Industry Awards

The 2011 national conference and industry awards, held at the Novotel Manly Pacific, Sydney, on 27-28 October 2011, was attended by over 170 delegates, speakers, media and guests. The conference was opened by the Parliamentary Secretary for Health and Ageing, Catherine King. In line with the CHC's strategic direction, she acknowledged the government's and the CHC's shared aspirations for the future health of the Australian population, and confirmed the integral role played by the CM industry.



Catherine King, MP

Delegates heard from more than 20 speakers about the latest research on prostate cancer and medicinal uses of fish oils, regulatory requirements for exports, the food-medicine interface, the political climate and CMs, IP protection and other insights into the future of the industry. The conference grabbed media attention, with representatives from *Pharmacy Daily*, *Pharma-in-Focus* and *Retail Pharmacy* in attendance. Also joining the conference were various exhibitors, including Plasdene Glass-Pak, NxGen and Unity Health. Delegates and their guests enjoyed a range of networking opportunities including the CHC golf day, welcome reception and annual industry awards dinner.



CHC executive director Wendy Morrow (L) with Blackmores' Amy Down



CHC president Richard Henfrey with Catalent's Mark Bissett and CHC executive director Wendy Morrow



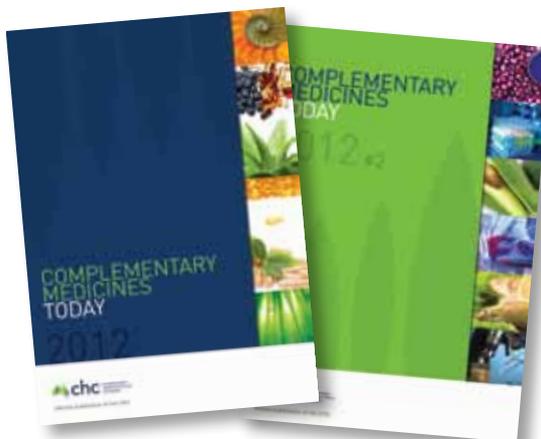
CHC executive director Wendy Morrow and Network Nutrition's Ryan Gorman

The tango-themed awards dinner celebrated achievements and successes of industry participants over the past 12 months. The winners were:

- **Lady Cilento:** Ronda Jacobs, former CHC president and former CEO of Catalent
- **Outstanding Contributor of the Year:** Chris Karabalis, Healthy Life, Woden
- **Industry Partner of the Year:** Network Nutrition
- **Outstanding Marketing Campaign:** Blackmores Sydney running festival
- **Manufacturer, Wholesaler or Distributor of the Year:** Catalent
- **Raw Material Supplier of the Year:** Pathway International
- **Vince Russell Retailer of the Year:** Chris Karabalis, Healthy Life, Woden, and Abraham Jones, Mr Vitamins
- **Best Consumer Publication** – **electronic, print or website:** Go Vita magazine
- **Outstanding Salesperson:** David Jones, Vitaco Health

Launch of Complementary Medicines Today (CMT)

The CHC's magazine, *Complementary Medicines Today*, was launched in conjunction with Roxby Media at the Sydney Hilton Hotel on 28 February 2012 in the presence of around 130 guests. *CMT* is the first B2B magazine focusing on Australia's high-growth, innovative, export-driven CM manufacturing industry.



Speakers included CHC president Richard Henfrey and representatives from Deloitte Access Economics, Swisse Vitamins and the University of South Australia. Lynne Pezzullo, director of Deloitte Access Economics, officially released the findings a report commissioned by the CHC into the economic merits of the preventive use of fish oils.



Deloitte Access Economics director Lynne Pezzullo

Media coverage of the findings was extensive, with the significant economic savings and public health benefits striking a strong chord.

Innovation, IP protection and marketing were also discussed at the launch, with speakers sharing their research, theories and experiences on potential new products, managing IP, advertising in Australia and the future direction of innovation.

2012 Parliamentary Reception

The Parliamentary Secretary for Health and Ageing, Catherine King, opened the CHC 2012 parliamentary reception at Parliament House Canberra on 20 March 2012 in the presence of around 90 industry leaders and fellow parliamentarians, including the Minister for Health Tanya Plibersek. Ms King focused on the future of the industry following the TGA reviews, and discussed the reforms resulting from the blueprint document, noting the importance of collaborative working and a consumer focus throughout implementation.

The CHC welcomed several other politicians and their advisers to the reception, including Joel Fitzgibbon, Shayne Neumann, Bronwyn Bishop, John Alexander, Barry Haase and Senator Claire Moore.

The reception was the platform for the introduction of the CHC's federal budget submission as well as its new consumer magazine, *Naturally Australia*. The independently written magazine provides advice to consumers on nutrition lifestyle and health, and directs readers to the accompanying Facebook page, website and social media apps.



Minister for Health Tanya Plibersek and CHC president Richard Henfrey

Swisse CEO Radek Sali and Lipa Pharmaceuticals CEO Dusko Pejnovic addressed guests at the reception, highlighting key aspects of the submission and touching on the current climate in innovation and manufacturing.



Swisse's Radek Sali (L), John Alexander, MP, Justin Howden, CHC, Catherine King, MP and Richard Henfrey, CHC

Successes with technical and regulatory affairs

The CHC supports appropriate regulatory reform that aims to increase efficiencies in the industry. We work collaboratively with the regulators to ensure industry's voice is heard. The CHC promotes the objectives of the Australian national medicine policy, which endeavours to bring about better health outcomes for all Australians, focusing in particular on people's access to and wise use of medicines.

Complementary medicine reforms – TGA blueprint report

The CHC's regulatory team has undertaken effective lobbying on behalf of members on regulatory and technical matters that impact on the industry. The past year has seen numerous regulatory reviews and proposals for reform. Of particular significance is the TGA blueprint report, which outlines the Australian government's response to several major reviews of therapeutic goods regulation, a process of reform set to continue over the next three years.

The CHC provided the TGA with a comprehensive response to the report – a report encompassing more than 60 recommendations from reviews, including the Australian National Audit Office performance audit review, the transparency review, advertising reforms, the promotion of therapeutic products working group and the informal group examining complementary medicines regulation.

The CHC is pivotal in shaping the policy agenda. The government is in the process of establishing the Therapeutic Goods Advisory Council later this year, which should see the CHC continuing to work closely with the regulator to provide strategic advice to the TGA.

Evidence required to support indications for listed medicines

The CHC harnessed the wide-ranging skills of our industry to develop its comprehensive submission to the consultation on the evidence required to support indications and claims for listed medicines (May 2012). The council lobbied the government for reasonable timeframes for consultation, and within a five-week period consulted key industry members to draft a comprehensive critique of the consultation draft, together with suggestions for improvements, including streamlined templates and industry-appropriate evidence sources.

ANZTPA and New Zealand Natural Health Products Bill

The Australia New Zealand Therapeutics Products Agency will eventually absorb both the TGA and New Zealand's Medsafe in a joint scheme for trans-Tasman regulation of therapeutic goods, yielding efficiencies in both countries. This process of integration has begun with a program of work-sharing and increased joint operations. Of particular interest to the industry is the progression of the Natural Health Products Bill in the New Zealand parliament. This offers the opportunity for in-depth discussion across the industry as to the most appropriate regulatory framework for both countries.

CHC policy and technical committees and working groups

The regulatory team continues to progress the CHC's strategic goals by facilitating members' access to collaborative decision-making on regulatory and standards issues through working groups and committees.



Codes of practice and industry guidelines

The complementary medicine industry is mature and responsible. The CHC strongly supports self-regulation that provides a framework to guide ethical behaviour by industry participants. Although non-members are not obliged to abide by the CHC codes, they are strongly encouraged to do so.

Marketing complementary medicines and health food products

The CHC, through its marketing code governance committee, practitioner medicine technical committee and executive board, has revised its code of practice for the marketing of complementary medicines and health food products to align with other key therapeutic industry codes of conduct.

As members may be aware, the government has proposed that the industry strengthen and standardise self-regulation through the development of an industry framework based on a common set of high-level principles. Subsequent to the work of the working group on the promotion of therapeutic products to develop this set of principles, the CHC marketing code has been rewritten to achieve consistency with these principles and to address the promotion of complementary medicines to healthcare professionals.

The revised CHC marketing code is undergoing a further phase of internal and external consultation to ensure that key issues have been addressed. The code has a target publication date of 1 January 2013.

Complementary medicines retailer's code of practice

The complementary medicines retailer's code of practice is intended to establish the basic principles and practices that deal fairly with relationships between retail members and customers, as well as relationships between retail members and other stakeholders within the industry. The retail advisory committee agrees that the maintenance of high standards is vital as complementary medicine becomes more integrated with mainstream healthcare as an effective preventative strategy to improve the wellbeing of the community and reduce our nation's healthcare costs.

A draft of the code is undergoing internal and external consultation, and is due for publication on 1 January 2013.

Code of conduct

The CHC code of conduct is intended to establish the basic principles and professional obligations that serve to protect consumers, and to identify the expectations of members with respect to other members and their activities. A primary draft has been reviewed by the executive board and a consultation draft will be shared with members and external stakeholders during the upcoming year.

CHC guideline for the sale and supply of practitioner-only products

The guideline for the sale and supply of practitioner-only products has been published on the CHC website, with the objective of providing guidance to the



complementary medicine industry on the appropriate content of practitioner-only product guides and technical manuals.

The practitioner medicine technical committee contributed to the development of this guideline, with additional input from the secretariat and from TGA advertising unit representatives.

CHC guideline for the quality and safety of raw materials used in complementary medicines

The guideline for the quality and safety of raw materials used in complementary medicines was published in 2012, and launched in two stages, the first being two member-only workshops held in Sydney and Melbourne, and the second to members and suppliers at the CHC regulatory obligations seminar in May.

The guideline is intended to be followed by industry to minimise the risk of breaching relevant legislation, enhance consumer confidence in the quality and safety of complementary medicines, and maintain and enhance the credibility and sustainability of the industry.

Advertising compliance and complaints resolution

The complaints resolution committee (CRC) is established under the CHC code of practice for the marketing of complementary healthcare and health food products to manage the co-regulatory system for the marketing of complementary medicines to consumers and healthcare professionals. It covers:

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

The CHC acknowledges and extends its appreciation to the Therapeutic Goods Administration for its support for the CRC over the past year.

The CHC thanks all CRC members and commends them for their dedication.

Complaints resolution committee, 2011-2012

- Les Dell**, Direct Selling Association of Australia (chair)
- John Baker**, Go Vita Springwood
- Philip Daffy**, Blackmores
- Michael Apollonov**, NSW Food Authority
- Raymond Khoury**, practitioner
- Petra Henniger**, PharmaCare Laboratories
- Norah McGuire**, consumer
- Wendy Morrow**, CHC
- Virginia Deigan**, TGA (observer)
- Janine Curll**, NSW Food Authority (alternate)
- Mick O'Connor**, TGA (alternate observer)
- Peter Ochsenham Brauer**, (alternate professional)
- Reg Lehmann**, Integria (alternate)

Summary of complaints, 2009-10 to 2011-12

Year	Complaints against CHC members			Complaints against non-members			Total		
	2011-12	2010-11	2009-10	2011-12	2010-11	2009-10	2011-12	2010-11	2009-10
Received	4	4	5	21	27	28	25	31	33
Finalised							16	35	41
Multiple complaints	1	1	1	1	1	0	2	2	1
Forwarded to TGA	0	2	2	5	5	4	5	7	6
Referred to CRP	1	1	1	3	8	8	4	9	9

Notes:

1. Complaints finalised in 2011-12 included nine complaints carried forwarded for determination from 2010-11.
2. Multiple complaints are the number of companies against which more than one complaint was received.
3. Complaints forwarded to the TGA are as per Code of Practice clause 8.4.4 where a complaint involves risk to public safety or the therapeutic good has not been included in the Australian Register of Therapeutic Goods.

Complaints resolution committee decisions

Of the 25 complaints received in 2011-12, the committee substantiated eight, did not substantiate two, and referred 13 to the TGA, CHC complaints resolution panel (CRP) or food authority. (Note that some complaints had more than one outcome – for example, they were substantiated and referred – and others had not been considered in the reporting period.)

CHC submissions

Over 2011-12 the CHC developed and lodged detailed submissions to the Therapeutic Goods Administration, Food Standards Australia New Zealand and several other authorities on various matters relating to the industry, its priorities and concerns.

Therapeutic Goods Administration

- CHC's correlation of responses to the TGA's blueprint report (April 2012)
- labelling and packaging review draft consultation paper (May 2012)
- prototype of the database of adverse event notifications (May 2012)
- draft guideline on evidence required to support indications for listed medicines (excluding sunscreens and disinfectants) and industry combined regulation impact data (May 2012)

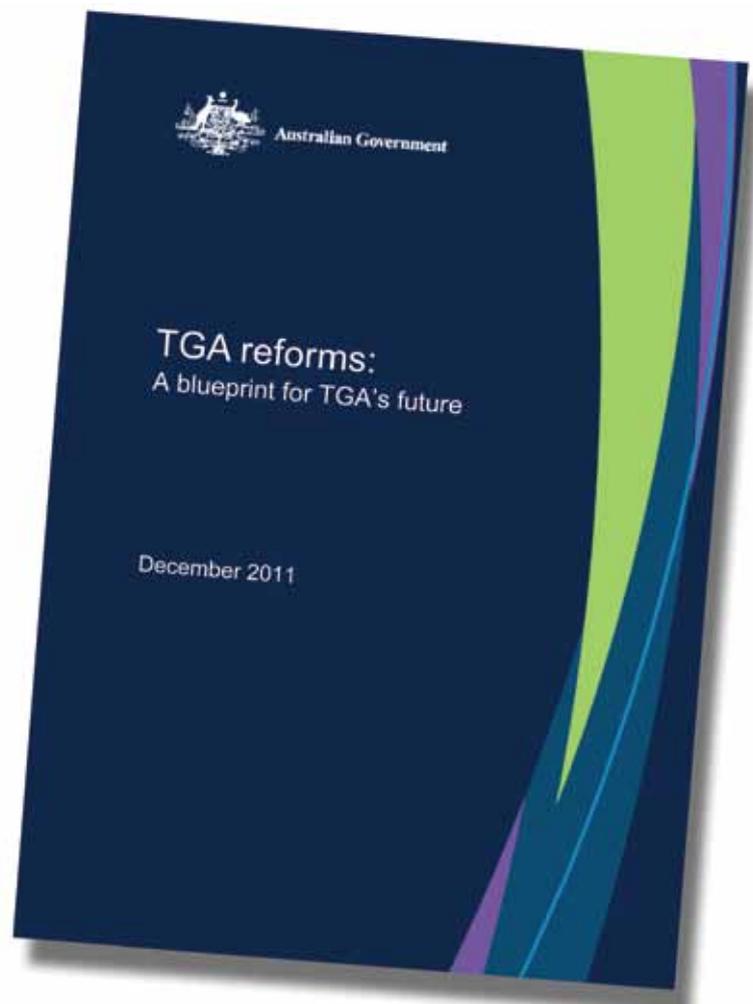
Food Standards Australia New Zealand

- scoping study for the review of nutrient reference values for Australia and New Zealand (including recommended dietary intakes) (January 2012)
- Proposal P293: Nutrition, health and related claims (March 2012).
- proposed future regulation of nutritive substances and novel foods in the Australia New Zealand Food Standards Code (May 2012)
- food regulation, labelling and advertising (November 2011)
- Proposal P242 Foods for special medical purposes (December 2011)

Government stakeholder submissions

- CHC's 2012-13 federal pre-budget submission (January 2012)
- Department of Industry, Innovation, Science, Research and Tertiary Education on refreshing the national research priorities (March 2012)
- National Health and Medical Research Council strategic review of health and medical research (March 2012)
- NSW Government manufacturing industry action plan: complementary medicines (December 2011)
- Department of Agriculture, Fisheries and Forestry consultation on the draft codex standard for fish Oils (December 2011)

Please contact the CHC for copies of any of the above submissions, as well as submissions from previous years.



Professional development

Seminars

The CHC also continues to support Members in maintaining an up to date awareness of the latest developments in Industry and support their professional development through our regular educational seminars, including the pharmacovigilance seminar (September 2011) and regulatory obligations seminar (May 2012).

Pharmacovigilance Seminar

Following the release of the TGA's *Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Medicines* in September 2011, the CHC and ASMI recognised the need for an educational seminar for industry participants. Around 50 delegates met in Canberra for the pharmacovigilance seminar on 9 September 2011 to hear from speakers including Jane Cook, head of the TGA's Office of Product Review. The seminar aimed to assist industry in understanding their pharmacovigilance responsibilities following the amendment of the guideline to incorporate listed and registered non-prescription medicines. Dr Cook provided an overview of the amended guideline and discussed the implementation and expectations of the guideline. Practical presentations were then provided to industry members on how to structure and manage a robust pharmacovigilance system.

Regulatory Obligations Seminar

With significant levels of regulatory reform affecting industry, TGA chief operating officer Jill Jepson opened the **regulatory obligations seminar** at North Sydney on 22 May 2012, and provided delegates with an overview of the TGA reforms currently under way. Over 100 delegates heard from 15 speakers representing government, industry and academia. These were led by the head of the TGA's Office of Complementary Medicines (OCM), Trisha Garrett, and the TGA's medical adviser, Michael Dodson, who introduced delegates to the OCM's implementation plan for the Australian National Audit Office's report recommendations and tackled the issue of evidence requirements. Other speakers, including CompleMED director Professor Alan Bensoussan, also confronted critical industry issues, as well as providing delegates with the latest updates on IP protection and Indigenous medicines clinical trials. Seminar delegates were joined by around 40 additional guests during the afternoon session for the joint launch of the CHC and ASMI guidelines around raw materials suppliers and good supplier practice.

Education

Facilitating the building of skills and knowledge within the workforce is a vital role of the CHC, especially at the consumer front line. In 2011-12 the CHC successfully broadened its diploma course target to include pharmacists.

In addition the CHC has launched an introductory certificate in complementary medicines, which provides a concise overview of key CMs and relevant industry information. The course is designed to meet the needs of those such as retail and pharmacy assistants who are the first point of contact for consumers.

The suite of CM certificate courses now comprises:

- introductory certificate in complementary medicines
- foundation studies for complementary healthcare products
- complementary healthcare products – nutritional supplements
- complementary healthcare products – herbal supplements
- complementary healthcare products – homoeopathics and herbal essences

A further two certificate courses will be launched soon:

- complementary healthcare products – therapeutics
- complementary healthcare products – sales and advertising

The certificates can be completed separately. Together the six courses (excluding the introductory certificate) will comprise the diploma of complementary healthcare products.

The courses are easily accessible through on-line delivery, allowing self-paced learning with access to the on-line tutor. In addition to course study materials, students have access to the Natural Standard database, which provides high-quality, evidence-based information on CMs. The CHC offers flexible payment options to meet student requirements so they can start studying sooner. Further information on any courses offered by the CHC is available at <http://moodle.chc.org.au/> or by emailing education@chc.org.au

Consumer communication

A key role for the CHC is helping consumers make informed health choices. The introductory certificate in complementary medicines also targets a broad consumer audience – those who wish to be better informed about CMs and those looking for career opportunities.



Building our base

The CHC has maintained its presence as the peak industry body for complementary medicines in 2011-2012. Through engagement with all facets of the industry, the CHC is well placed to represent its members in the changing dynamic facing the industry.

Through engaging our members in working committees, we ensure that they are actively involved in the strategic direction of the industry.

Engaging our members

Membership is an essential component of the CHC strategy. We aim for continued growth of our member base and to maintain satisfaction among our current members. New members are encouraged to become involved, as new ideas and approaches are always warmly welcomed.

The secretariat has been actively encouraging our members to be more involved in CHC activities. The involvement of members will help in shaping the political agenda, driving key strategies and developing industry-focused initiatives. Through events such as our parliamentary reception, members have the opportunity to network with politicians, media and other CHC members. These interactions are invaluable in developing industry cohesiveness and morale.

Membership benefits and services

Members of the CHC are offered a wide range of benefits and services to complement their business. We run annual events where members receive either discounts or complimentary registrations aimed at encouraging attendance and involvement in the industry. The widening range of interests of member companies demonstrates an increased awareness of the benefits and strengths of the CHC. The unparalleled support offered through regulatory reform updates, technical updates, industry news and media releases is targeted to our member companies, and highlights current issues and industry developments that may affect their business.

We welcome feedback from members and encourage interaction within both the membership base and the industry as a whole. Through member interaction and feedback, the CHC continues to grow and strengthen its role as the peak industry body for complementary medicines in Australia.

Looking ahead

The publication of the government's blueprint for the future of the TGA in December 2011 set the regulatory agenda for the coming months and years that will keep us all fully occupied. The CHC has been consulted on and engaged in many of the reports that formed the basis for the blueprint. We support the top-level recommendations contained in the blueprint. We recognise that we have a unique opportunity to address some of the familiar issues surrounding the regulation of complementary medicines, and we will continue to work for the judicious implementation of the recommendations.

CHC is the voice of industry

In addition to regulatory action, the CHC will continue to build and strengthen its political and industry development platforms. We continue to drive the growth of the CHC through our strategic plan, as developed by you, the members of the CHC.

The key issues we will continue to focus on include enabling the "informed" consumer; political engagement and policy shaping; ensuring consistency and fairness of regulation; reviewing our codes of practice; and positioning the industry with the media and policy-makers.

We look forward to working with our members on these issues and more over 2012-2013 to shape and advance the complementary medicine industry in Australia.

