

Australian Skeptics



A Big Mac and fries needs 5 Undoit® pills.

TGA Reform: the Impact of Civil Society Activism

Dr Ken Harvey MB BS, FRCPA
<http://www.medreach.com.au>

Victorian Skeptics, La Nette, Feb 20, 2012



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TGA Reviews 2010-11



- Australian Government. Working Group on Promotion of Therapeutic Products.
- TGA Consultation. Improving advertising arrangements for therapeutic goods.
- Australian Government. TGA Transparency Review Panel.
- Australian National Audit Office. Therapeutic Goods Regulation: Complementary Medicines.
- TGA Working Group on Regulatory Framework for Complementary Medicines.
- Australian Government. TGA reforms: A blueprint for TGA's future.

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Regulation of promotion

“There is an integrated three-tier system of controls for the advertising of therapeutic goods in Australia”.¹

- Self-regulation (promotion to health professionals)
 - Industry Codes and complaints panels in various sectors, such as Medicines Australia, GMIA, ASMI, CHC, MTA, AusBioTech, IVD Australia, ADA, ACCORD.
- Co-regulation (promotion to consumers)
 - Therapeutic Goods Advertising Code (TGAC), Complaints Resolution Panel (CRP) and TGA.
- Regulation (legislation)
 - *Therapeutic Goods Act 1989* (TGA) and *Trade Practices Act, 1974* now renamed the *Competition and Consumer Act 2010* (ACCC).

1. <http://www.tgacrp.com.au/>

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Case study: Actonel EC



Howard Sattler
Perth radio station 6PR

- In June last year, prompted by press releases from Sanofi Associate Professor Charles Inderjeeth was interviewed by Howard Sattler on the Perth radio station 6PR to discuss osteoporosis treatment.

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Case study: Actonel EC


In this 7 minute radio interview, the brand name was specifically mentioned 15 times:

- “Now fortunately we have a novel new agent called *Actonel EC*” (CI),
- “*Actonel EC*” (CI),
- “So that has been a major advance and it implies that people can actually have this tablet, *Actonel EC*, first thing in the morning with their breakfast...” (CI),
- “...these are patients who would all qualify for access to *Actonel EC*...” (CI),
- “if you’ve had bone fractures, that qualifies you then to take the – to get the *Actonel EC*?” (HS),
- “... what does *Actonel EC* do for you?” (HS),
- “...now we’re going to have a heap of people call this program and say, what was that, didn’t hear that? It’s *A-c-t-o-n-e-c-i*, is it?” (HS),
- No it’s *A-c-t-o-n-e-c-i*” (CI),
- “*A-c-t-n-o-l?* ei” (HS),
- “*A-c-t-o-n-e-c-i*” (CI),
- “And then a capital E and a capital C so it’s called *Actonel EC*” (CI),
- “*Actonel EC*” (HS).

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Case study: Actonel EC



- Any activity directed towards the general public which encourages a patient to seek a prescription for a specific prescription only product is prohibited (12.3)

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Australian Skeptics Case study: Actonel EC

Table of finalised complaints where activity directed at the general public, for complaints finalised in February 2012

| No. | Subject Company | Material/Activity | Product | Complainant | Outcomes* | Sanction |
|------|-----------------|-------------------|------------|-------------------------|-------------------------------------------------------------------------------------------------------------------------|----------|
| 1077 | sanofi-aventis | Media segment | Actonel EC | Healthcare Professional | <ul style="list-style-type: none"> Breaches of Sections 12.3 and 12.4 No breach of Section 9.13 | \$40,000 |


<http://medicinesaustralia.com.au/files/2010/01/20120214-rep-gen-pub-activities-Jan-Feb2012.pdf>

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Australian Skeptics Problems with self-regulation

MA system has incrementally improved over 16 Editions, however:

- Removing drug advertisements from prescribing software required submissions from many parties and took several Code revision cycles.
- ACCC action was needed before MA disclosed money spent on "education and hospitality".
- MA still refuse to disclose payments to health professionals.



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Australian Skeptics Compare with U.S.

- Merck discloses \$3.7m paid to U.S. doctors for speeches over three months¹
- This follows Eli Lilly in disclosing payments to doctors who speak for companies.
- Pfizer and GlaxoSmithKline have promised to make similar disclosures.
- Physician Payment Sunshine Act (March 30, 2010)²
 - The U.S. government now requires yearly reporting of all physician payments (cash or kind) over a cumulative value of \$100 dollars - with the first report being due by 2012.


- http://www.bmj.com/cgi/content/full/339/oct26_1/b4409
- http://www.prescriptionproject.org/sunshine_act/

Australian Skeptics Problems with self-regulation

Weak sanctions

- Pfizer Australia had 16 complaints upheld against MA Code over 2005-09; fines averaged only A\$50,000.
- Compare this with the U.S Justice Department who recently fined Pfizer a total of US \$2.62 billion for repeated unethical conduct.¹

- <http://tinyurl.com/vccfplu>



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Australian Skeptics Problems with self-regulation



Australian Skeptics Problems with self-regulation

- Numerous sector based industry Codes make it difficult to know where to send complaints.
- Codes often lag behind consumer and health professional views due to the absence of external stakeholders.
- Code content, monitoring, complaint procedures and transparency vary across industry sectors ("not a level playing field").
- Codes don't apply to non-members; a major problem with complementary medicines.

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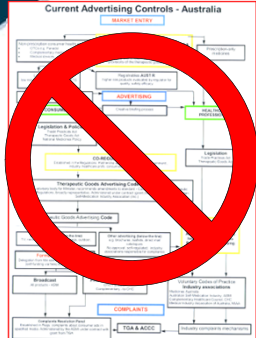
Problems with self-regulation




- Following media stories about a Sigma “educational” luxury cruise for pharmacists and GPs the then Parliamentary Secretary for Health Mark Butler said:
 - “The Government is pursuing a level playing field on marketing obligations within the therapeutic goods industry”

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What many advocated

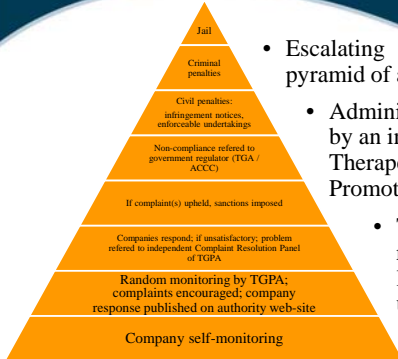


- One Code, one efficient educative, monitoring, complaint (and appeal) system and one set of effective sanctions applicable to all promotional activities about therapeutic goods.

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What many advocated



- Escalating pyramid of action.
- Administered by an independent Therapeutic Goods Promotion Agency.
- TGA product registration and listing dependent upon compliance.

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Working Group on promotion

| | |
|-------------------|-----------------------------------------------------|
| Anne Trimmer | Medical Technology Association of Australia (Chair) |
| Anna Lavelle | AusBiotech |
| Troy Williams | Australian Dental Industry Association |
| Dr Roderick McRae | Australian Medical Association |
| Elizabeth Foley | Australian Nursing Federation |
| Dr Deon Schoombie | Australian Self Medication Industry |
| Dr Wendy Morrow | Complementary Healthcare Council of Australia |
| Carol Bennett | Consumers Health Forum of Australia Inc |
| Kate Lynch | Generic Medicines Industry Association |
| Dr Peter Harman | IVD Australia |
| Dr Brendan Shaw | Medicines Australia |
| Mark Feldschuh | Pharmaceutical Society of Australia |
| Anne Develin | Pharmacy Guild of Australia |
| Mary Osborn | Royal Australasian College of Physicians |
| Dr Ken Harvey | School of Public Health, Latrobe University |

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Working Group Report




- Working Group on Promotion of Therapeutic Products (to health professionals) delivered its report to Parliamentary Secretary Catherine King on 18 March 2011.
- High level statement of principle:
 - the Australian therapeutic products industry promotes the concept of good health incorporating the quality use of therapeutic products based on genuine consumer health needs and supported by the ethical conduct of all parties.

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Working Group Report



- The working group recommended that each therapeutic industry sector code address:
 - **Specific operational areas**, such as industry-sponsored educational events, conduct of representatives, hospitality and entertainment, and social media.
 - **Governance areas for the effective implementation of the code:**
 - Education on the code’s operation;
 - Monitoring of compliance with the code;
 - Enforcement of the code in response to a complaint or a breach;
 - Sanctions to support the enforcement (at a level that deters non-compliance).



Australian Skeptics Working Group Report



- The working group addressed the need for adherence to industry codes by non-members by recommending that all applicants nominate the relevant code of practice to which it will subscribe, as a condition of registration/listing/inclusion of a product on an AUSTL.
- The working group notes that Government's intention is for the 'sign on' process to be voluntary at the first instance.
- The working group is concerned that voluntary nomination may not be effective to achieve the Government's objectives and that code nomination should be made a mandatory part of product registration.

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Australian Skeptics Working Group Report

- The working group recommended the establishment of a process to evaluate, on an ongoing basis, the implementation of the recommendations of the working group.
- In particular the evaluation should address process, impact and outcome performance indicators set out in Appendix C of the report.

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Australian Skeptics What to do?



Medicines Australia Code of Conduct Consumer Workshops Registration Form

Please Fax to Sophie Hibburd on (02) 6122 8555 or return via email to secretarycodecommittee@medicinesaustralia.com.au

I would like to attend the Code Consumer Workshop in

| | | |
|-----------|----------------------------------------------|--|
| SYDNEY | Monday 12 March, 2012 (10:00 am – 3:30 pm) | |
| MELBOURNE | Wednesday 28 March 2012 (10:00 am – 3:30 pm) | |

To assist Medicines Australia in organising the workshops please complete the following information:

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Australian Skeptics ACCC authorisation



Medicines Australia Inc - Authorisations - A90994-A90996

| | |
|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Outcome | Appeal finalised - granted with conditions |
| Applicant(s) | Medicines Australia Inc(formerly APMA) |
| Authorisation number(s) / Date lodged | <ul style="list-style-type: none"> A90994, 30th November 2005 A90995, 30th November 2005 A90996, 30th November 2005 |
| Summary | <p>Medicines Australia lodged an application to revoke authorisations A90775-A90780 relating to Edition 14 of its Code of Conduct and their substitution with authorisations A90994-A90996 in respect of Edition 15 of its Code of Conduct.</p> <p>The ACCC granted conditional authorisation for three years to Medicines Australia on 26 July 2006. Medicines Australia applied to the Australian Competition Tribunal for a review of the ACCC's determination. The Tribunal released its determination on 27 June 2007. The Tribunal affirmed the ACCC's determination subject to minor amendments to the condition of authorisation and granted authorisation to the Code for 5 years. A copy of the Tribunal's determination is available from the Tribunal's website.</p> |

pharma
phacts

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Australian Skeptics Regulation of promotion

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1. <http://www.tgacrp.com.au/>


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Australian Skeptics What do consumers want?



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Australian Skeptics Registration compared to Listing



- The TGA uses a risk-based pre-market assessment of therapeutic goods.
- Registered medicines (labelled AUST R) are said to be thoroughly evaluated for quality, safety and efficacy prior to market release.
- All prescription medicines are AUST R.
- Listed medicines (labelled AUST L) are regarded as lower risk self-medication products. They are required to meet quality and safety standards but are not assessed for efficacy.
- Most CMs are listed (AUST L) on the ARTG.

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Australian Skeptics Listing




- The TGA's electronic listing facility (ELF) allows rapid and low cost entry onto the ARTG.
- Sponsors self-certify via ELF that:
 - Their product is manufactured according to GMP standards;
 - The ingredients are picked from a consolidated list that the TGA regards as relatively low risk;
 - Their products only carry indications and claims for the symptomatic relief of conditions (but not for proscribed serious disease, disorders, or conditions), health maintenance, health enhancement and risk reduction;
 - They hold evidence sufficient to substantiate that the indications and claims are true, valid and not misleading.
- Limited random and targeted post-marketing surveillance is performed.

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Australian Skeptics Problems

- Low fees and automated market approval (ELF) encourage sponsors to List rather than Register products with the TGA.
 - Listing allows sponsors to self-name, self-certify and self-enter "free-text" information on the ARTG, e.g. *HungerBuster*, "Facilitates the body's natural fat burning processes".
- A 2009-10 post-marketing review (of 31 randomly selected complementary medicines) was cited in the ANAO report:
 - 20 (65%) had non-compliance with labelling requirements and/or breaches which may mislead consumers.
 - 22 (71%) were found to have manufacturing and/or quality issues.
 - 14 (45%) did not have adequate evidence to substantiate claims made.

Australian Skeptics Problems



- In short, a system based on trust has been shown to fail.
- Removal of products from the ARTG by the TGA for regulatory non-compliance (after protracted due process) does not necessarily stop continued promotion and use.
- In addition, sponsors can readily relist (after minor changes).
- Unscrupulous sponsors know that the TGA is a paper tiger and the current system can be gamed to their commercial advantage.

Australian Skeptics SensaSlim

Home > News room > News & public notices >>

Cancellation of Sensaslim Solution from the ARTG

24 November 2012

The TGA has cancelled the listing of Sensaslim Solution (AUST L 176003) from the Australian Register of Therapeutic Goods (ARTG). The cancellation is because of a failure to comply with requirements of the Therapeutic Goods Act 1989 relating to the advertising of the product.

| Timeline | |
|--------------|--------------------------------------------------------------------------------------|
| Jan 26, 2011 | The first if many complaints submitted to regulators |
| Apr 19, 2011 | NSW defamation action initiated by SensaSlim Pty Ltd to stop complaint being heard |
| Aug 15, 2011 | NSW defamation claim struck out; QLD defamation action against complainant initiated |
| Nov 24, 2011 | TGA cancelled ARTG listing |
| Nov 29, 2011 | Sensaslim still being sold, more complaints submitted to TGA |
| Feb 10, 2012 | QLD defamation strike out application successful |
| Mar 12, 2012 | Directions hearing in Federal Court, ACCC vs SensaSlim |

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SensaSlim

DISSOLVED

07070655 SENSASLIM INTERNATIONAL LIMITED

This Company was dissolved on 21/02/12

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Meanwhile, others see the market opportunity

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Meanwhile, others see the market opportunity

undoit[®]
removes fat and carbs

- "A tub of ice-cream may need 2 pills."
- "A big sugary/fatty dessert will need 3 pills."
- "And a Big Mac and fries will need 5 pills."

Have your cake....

...and eat it too

<http://www.undoit.com.au/>

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TGA Undoit[®] response

20 February 2012

The TGA has *noted* your complaint in relation to Undoit. The TGA *may use* this information and conduct investigations in relation to the safety, quality and regulatory status of the goods.

Please note that *you may not be informed* of the outcome of any investigations *as the information may be confidential to the owner of the medicine.*

Trisha Garrett | Head Office of Complementary Medicines trisha.garrett@tga.gov.au

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Problems

- The current "light-touch" regulation of CMs, especially the lack of timely and significant penalties for breaches of the Therapeutic Goods Advertising Code and the Therapeutic Goods Act, encourages unscrupulous sponsors to flood the market with shonky products.
- The TGA (and industry) has failed to educate consumers and health professionals that CMs (especially herbals) are usually complex products and the concept of therapeutic equivalence of generic ingredients that is applicable to PBS products does not apply to CMs.
- Just as all red wine is not Grange Hermitage neither are all preparations of St John's Wort, or glucosamine for example, therapeutically equivalent. Clinical trial results only apply to the specific, well characterised product that was tested, they CANNOT be extrapolated to other products containing the same generic ingredient.

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Problems

Of the 328 formulations of glucosamine on the ARTG; what should I choose and/or recommend?

Vlad SC, LaValley MP, McAlindon TE, Felson DT. Glucosamine for pain in osteoarthritis: why do trial results differ? Arthritis Rheum 2007;56:2267-77.2. Rejnster JY. The efficacy of glucosamine sulfate in osteoarthritis: financial and nonfinancial conflict of interest [editorial]. Arthritis Rheum 2007;56:2105-10.

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choice
THE PEOPLE'S WATCHDOG

18 October 2011

Dr Rohan Hammett
National Manager
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Dr. Hammett,

Re: A TGA list of registered (and properly evaluated) Complementary Medicines (CMs)


The recent Australian National Audit Office (ANAO) report titled, "Therapeutic Goods Regulation: Complementary Medicines" said (43):

"It would enhance transparency and help inform both consumers and healthcare professionals if the TGA were to place the summary of evidence it collects from sponsors, as received, on its website—with a clear indication of whether it had been assessed or evaluated by the TGA."

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Recently registered CMs include:



- Flordis Iberogast (a clinically proven nine herb mixture) for Irritable Bowel Syndrome.
- Blackmores Flexogil Pain Relief cream (a clinically proven comfrey root extract) for the topical treatment of sprains and osteoarthritis.

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From: Ian.Stehlik@tga.gov.au [mailto:Ian.Stehlik@tga.gov.au]
Sent: Friday, 3 February 2012 1:03 PM
To: Ken Harvey
Cc: Trisha.Garrett@tga.gov.au
Subject: List of evaluated registered complementary medicines [SEC=UNCLASSIFIED]

Dear Ken

We have completed work on the proposed list which is going through a 'clearance for publication' process within TGA at present. I'm sorry I can't give you an immediate indication of the timing of release just yet.

Ian

Ian Stehlik | Head, Office of Complementary Medicines | Therapeutic Goods Administration | * 02 6232 8439 | 7 02 6232 8577 | m. 0413 644 243 | * ian.stehlik@tga.gov.au

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Problems

- AUST R labelling for CMs is flawed by grandfathering unevaluated products.
- The TGA is yet to produce a list of properly evaluated registered CMs (although this is underway).
- Research has shown that the public does not understand the difference between AUST R and AUST L labelled products.
- Thus, there is currently little incentive for sponsors to undertake expensive research, compile an extensive dossier and pay the higher fees required for TGA registration.
- A better return on investment comes from spending the money on marketing.

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Problems




- TGA consultations on regulatory reform have been opposed by industry and never brought to a conclusion. For example:
 - Regulation of homeopathic and anthroposophic medicines in Australia (2008)
 - Guidelines for Levels and Kinds of Evidence for Listed Medicines with Indications for Weight Loss (2009)

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Relevant ANAO recommendations

- To achieve timely completion of key guidance material for CMs, the ANAO recommends that DoHA:
 - Provides a target date for the completion and publication of each key guidance document [especially evidence requirements].
 - Provides regular progress reports on the development of key guidance documents, on the TGA website, to keep industry, health professionals and consumers informed.

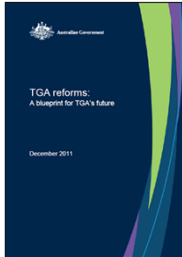


Australian Skeptics Key solutions advocated

- Mandatory labelling, “This product has **NOT** been evaluated by Australian Health Authorities to see if it works”.
- Summaries of sponsor’s “evidence” for Listed products to be made available on the ARTG web site.
- Distinguish the few properly evaluated Registered complementary medicines from the many that were “grandfathered” into the ARTG.
- Increased and better targeted post-marketing surveillance and transparent reporting of problems and cancellations.
- Legislate for timely and meaningful sanctions for advertising violations (civil penalties, enforceable undertakings). 43

Australian Skeptics What did we get?

- The TGA will:
 - Better explain that low risk products are not evaluated for effectiveness.
 - Create a central point for advertising complaints, deal directly with complaints regarding efficacy and publish the outcome of certain investigations into complaints.
 - Develop options for government on more effective sanctions and penalties for both advertising and regulatory compliance breaches
 - Update and include in regulations the 2001, *Guidelines for the levels and kinds of evidence to support indications and claims.*
 - Work with stakeholders to develop options to improve labelling.



Australian Skeptics Resignation of Dr Rohan Hammett

23 December 2011

The Parliamentary Secretary for Health, Catherine King, thanks the retiring National Manager of the TGA Dr Rohan Hammett for his committed and very professional service.

Dr Hammett has successfully overseen a significant period of development within the organisation which culminated late this year in a decision by the Government to embark on a comprehensive set of reforms, to be put in place in the next four years, to further increase the transparency and efficiency of the TGA.

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Australian Skeptics Resignation of Ian Stehlik

5 February 2012

Following some career decisions that I took towards the end of last year, I will be retiring from TGA and the Australian Public Service (APS) after a period of leave which commences on 6 February 2012.

Ms Trisha Garrett will be taking up the role of Head, Office of Complementary Medicines (OCM) from 6 February.

Ian Stehlik | Head, Office of Complementary Medicines | Therapeutic Goods Administration

Australian Skeptics Conclusion

- Civil society (skeptics, consumers, health professionals) have put in many submissions to TGA and government reviews.
- Regrettably, a ton of effort has only produced an ounce of movement.
- However, there are ongoing opportunities to keep the pressure up (MA Code consultations, ACCC Code authorisation, forthcoming conferences and by submitting continued complaints.
- The TGA and government must be held to account.

ASIA PACIFIC CONFERENCE ON **NATIONAL MEDICINES POLICIES**
 Better Health Through National Medicines Policies
 SYDNEY AUSTRALIA 26-29 MAY 2012

| | |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| HOME | Improving pharmaceutical promotion in Australia (APCNMP 2012) |
| CONFERENCE OVERVIEW | Background |
| SCIENTIFIC PROGRAM | Ethical promotion is a key building block of the Australian Quality Use of Medicines (QUM) Strategy. |
| SCIENTIFIC PROGRAM COMMITTEE | Its importance was reiterated by World Health Assembly Resolution WHA 60.16 which urged member governments to “Enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines” and “Monitor drug promotion”. |
| CALL FOR ABSTRACTS | Objectives |
| ABSTRACT SUBMISSION | Assess the nature and extent of Australian pharmaceutical promotion controls and their impact on promotional practices |
| POSTER GUIDELINES | Conclusions |
| FUNDING SUPPORT | The Australian government has failed to implement WHA resolution 60.16 and QUM suffers as a result. |
| REGISTRATION | |
| ACCOMMODATION | |
| COLLABORATING PARTNERS | |
| VENUE AND HOST CITY | |