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The 2015 Review of Medicines and Medical Devices Regulation: Government Response

Dr Ken Harvey MB BS, FRCPA
Adjunct Associate Professor, School of Public Health and Preventive Medicine
http://www.medreach.com.au

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MONASH University

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Disclosure of interests

- Member:
  - WHO Ethical Criteria for medicinal drug promotion.
  - Therapeutic Guidelines Limited.
- Consumer rep (Choice, CHF):
  - Government Working Group on Promotion of Therapeutic Products.
  - TGA Transparency Review Panel.
  - TGA Working Group on Regulatory Framework for Complementary Medicines.
  - Government Natural Therapy Review Advisory Committee.
  - Therapeutic Goods Advertising Complaint Resolution Panel & Code Council.

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MMD Review: Government response

Where is it?

Sansom silence a puzzle to all

pharma in focus

29 August 2016

- The two parts and 58 recommendations of the MMD Review were released in June & July of 2015 respectively.
- There was a brief mention of some broad-brush responses in the 2016-17 Budget Fact-sheets, but subsequently, nothing more!

PM's diary delaying Sansom response?

pharma in focus

30 August 2016

- It has been reported that government has agreed to most, but not all of the recommendations; the TGA has prepared options papers to be followed by further public consultations; then the election intervened; now the delay is said to be fitting the announcement into the PM's diary!

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MMD Review: Government response

Budget 2016-17
Fact-sheet 23
03 May 2016

REGULATION AND SAFETY

- The Government will bring life-saving medicines and medical devices onto the Australian market up to 2 years faster, through streamlining of processes and regulations and utilising comparable overseas regulators.
- There will be greater focus on post-market reporting to ensure safety and efficacy is maintained; this will include enhanced electronic reporting and a risk communication strategy.
- Commercial bodies approved by the TGA will be allowed to undertake medical device assessments.

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Some caveats

- The hazards of rapid approval of new drugs, Martin J, Shenfield G, Aust Prescr 2016;39:2-31 Feb 2016.
  - https://www.nps.org.au/australian-prescriber/articles/the-hazards-of-rapid-approval-of-new-drugs
- Problems with FDA post-marketing review processes. United States Government Accountability Office. December 2015.
  - http://www.gao.gov/assets/680/674183.pdf

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Some caveats

- Faster approval of new medical products heightens uncertainty over risk. AAAS News, 7 July, 2014.
  - https://www.aaas.org/news/faster-approval-new-medical-products-heightens-uncertainty-over-risks
- Comparison of rates of safety issues for medical devices approved in the European Union and United States: cohort study. Hwang TJ, et al., BMJ 2016;353:i3323.
  - http://www.bmj.com/content/bmj/353/bmj.i3323.full.pdf

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MMD Review: Government response

Budget 2016-17
Fact-sheet 23
03 May 2016

REGULATION AND SAFETY

- Advertising regulations will be simplified (eliminating pre-approval?) and made more consistent across the range of medicines and medical devices.
- TGA investigation and enforcement powers will be strengthened, and a new compliance education program for industry will be introduced.
- Compliance activities will make greater use of data analytics to target areas of concern.
- Design and IT systems changes will be drawn from reserves in the TGA Special Account (to cost $20.4 million from 2016–17 to 2019–20).
- An increase in TGA fees and charges will not be required.

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Background

World Health Assembly 2007

Resolution 60.16:

- Wishing to promote evidence-based rational use of medicines by providers and consumers;

- URGES Member States to:
  - Enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines,
  - Monitor drug promotion;
  - Develop and implement programmes that will provide independent, non-promotional information about medicines.

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Australia's response:

An integrated three-tier system of controls for the advertising of therapeutic goods

Regulation
- Therapeutic Goods Act 1989
- Therapeutic Goods Regulations 1990
- Competition and Consumer Act 2010

Co-regulation
- Therapeutic Goods Advertising Code 2015
- TGACC; TGACRP
- Therapeutic Goods Administration

Self-regulation
- Industry Codes of Conduct (9 Associations)
- Industry Complaint Panels
- But what about non-members?

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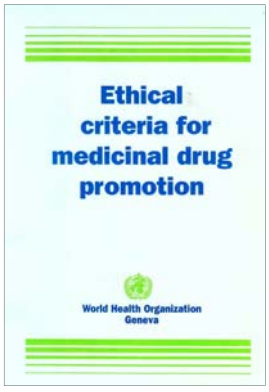
Advertising controls



- Direct to consumer advertising of prescription drugs is not allowed.
  - Although disease awareness and other campaigns push the boundaries.
- Therapeutic Goods Advertising Code applies.
  - Based on WHO Ethical Criteria.
  - Advertising should promote rational use, be socially responsible and not mislead or deceive.
- Limited pre-clearance of advertisements delegated to industry (ASMI, CMA).
  - Advertisements for medicines (but not medical devices).
  - In print, radio and TV (but not the Internet).

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Problems with the system

Where to complain?

- Complaints about advertisements for medicines or devices appearing *in radio, television, consumer magazines, newspapers, billboards, cinema or the Internet* may be sent to:
  - The Executive Officer, Complaints Resolution Panel
- Complaints about advertisements for *complementary medicines* (herbal preparations, vitamin or mineral supplements, or homoeopathic preparations) *appearing in publications such as leaflets, flyers, brochures, catalogues or letterbox drops* may be directed to:
  - The Secretariat, Complaints Resolution and Monitoring Committee, Complementary Medicines Australia
- Complaints about advertisements for *non-prescription medicines appearing in publications such as trade journals, leaflets, flyers, brochures, catalogues, letterbox drops or as part of a campaign* may be sent to:
  - The Secretariat, ASMI Complaints Panel
- Alternatively, complaints about advertisements may be sent to:
  - Advertising Compliance, Regulatory Practice, Education and Compliance Branch, TGA

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Problems with the system

Outcome of complaints

- The CRP is under-resourced, over-loaded and lacks power to enforce sanctions.
- It can take 4-12 months for complaints to be heard and the determination made public.
- Non-compliance with CRP "requests" is common; these are passed to the final regulator, the TGA.
- The TGA then conducts its own investigation which can take another 4-12 months. The outcome is often not made public.
- If the TGA agrees with the TGACRP they can issue a "Regulation 9 order" which is meant to compel compliance. But companies can (and do) appeal to the Minister &/or the Administrative Appeals Tribunal which further delays resolution.
- Meanwhile, misleading promotion continues.

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Problems with the system

Outcome of complaints

https://www.youtube.com/watch?v=jaQyrLzjvRs (2:06 minutes in)

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Problems with the system

Outcome of complaints

911 days later
(August, 2016)

http://www.sambucolaustralia.com/the-sambucol-range-49758.html
http://www.chemistwarehouse.com.au/buy/60462/Sambucol-Cold-Flu-24-Capsules
Etc.

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Problems with the system

ARTG Public Summary

TGA eBS

Public Summary

Summary for ARTG Entry:	178380	Sambucol Cold & Flu
ARTG entry for	Medicine Listed	
Sponsor	Pharmacare Laboratories Pty Ltd	
Postal Address	PO Box 384, MONA VALE, NSW, 1660 Australia	
ARTG Start Date	15/12/2010	
Product category	Medicine	
Status	Active	

Effective date: 28/06/2016

Clinically trialled*to shorten your cold by 3 days

Scientific studies have demonstrated that Sambucol reduces the severity of cold and flu symptoms and shortens the duration of a cold.

In a clinical trial, patients given Sambucol recovered on average 3 days faster compared to those given a placebo.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relating to such manufacture shall be

rds or copies of the records

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or adm of Product Review, Therapeutic Goods Administration, as soon as practicable after th of listed medicines must retain records of such reports for a period of not less than 18 of the report or reports.

CLINICALLY TRIALLED*

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Problems with regulation

- The lack of pre-market evaluation of the efficacy of most CM; especially the lack of timely and significant penalties for breaches of the regulations, encourages unscrupulous sponsors to flood the market with shonky products and unethical claims.
- Research has shown that the public does not understand the difference between AUST R and AUST L labelled products; nor "traditional" versus "scientific" evidence.
- Thus, there is currently little incentive for CM 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 celebrity endorsement and promotional hype.

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Media perceptions

http://www.youtube.com/watch?v=12ww26sQF7E&feature=youtu.be

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Rules under review?

Date	Initiative
2002	Report of a Review of Advertising Therapeutic Products in Australia and New Zealand
2003	Report of Expert Committee on Complementary Medicines in the Health System
2005	Description of the joint (Trans-Tasman) regulatory scheme for the advertising of therapeutic products
2006	Consultation (Draft) Regulation Impact Statement on the proposed amendments to the current regulatory system for herbal and homoeopathic medicines in Australia
2007	Consultation - draft (Trans-Tasman) advertising rule
2008	Regulation of homoeopathic and anthroposophic medicines in Australia
2009	Draft Guideline for Levels and Evidence for Listed Medicines with Indications & Claims for Weight Loss
2010	TGA Consultation: Improving advertising arrangements for therapeutic goods
2011	Consultation and Report of the Working Group on Promotion of Therapeutic Products Report of the Review to improve the transparency of the Therapeutic Goods Administration ANAO Report. Therapeutic Goods Regulation: Complementary Medicines TGA reforms: A blueprint for TGA's future
2012	Delivering reforms - Implementation plan for TGA Reforms TGA Advertising regulatory framework: Options for reform
2013	TGA Consultation Regulation Impact Statement: Regulating the advertising of therapeutic goods to the general public
2014	Expert Review of Medicines and Medical Devices Regulation (Government de-regulation agenda) Australian and New Zealand Governments agreed to cease efforts to establish a joint therapeutic products regulator
2015	Expert Review of Medicines and Medical Devices Regulation: recommendations and public forum.

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What did we want?

- A regulatory system with teeth!
- Mandatory labelling, "This product has ***NOT*** been evaluated by Australian Health Authorities to see if it works".
- Legislation for timely and meaningful sanctions for advertising violations (civil penalties, enforceable undertakings).
- Increased and better targeted post-marketing surveillance and transparent reporting of problems and cancellations.

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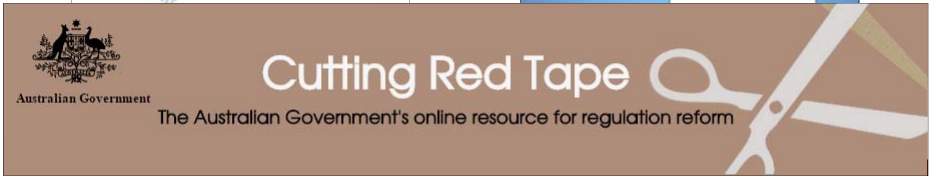
What did we get?

Another bloody review!



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What did we get?

TGA Listed medicine compliance reviews: 2015-16

- Increased post-marketing surveillance by the TGA continue to show appalling levels of industry non-compliance:
  - 72% for 315 random reviews and
  - 95% for 158 targeted reviews.
- The main issues, accounting for 80% of non-compliance, were labelling, advertising and evidence.
- In addition, for 2015-16, the TGACRP found 98% of 141 complaints justified (and a 40% non-compliance with TGACRP "requests" for redress).

http://www.tga.gov.au/sites/default/files/presentation-how-do-listed-medicines-shape-up-in-the-post-market-compliance-space.pdf

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Industry spin

- Consumer ask:
  - How can I be sure that a product is safe and effective?
- The industry answers:
  - Australia has a two-tiered regulatory system for therapeutic goods, based on risk. The TGA is responsible for the oversight of all therapeutic goods in Australia including complementary medicines.
- Which ignores the massive levels of industry non-compliance, both with TGA regulations and the Therapeutic Goods Advertising Code.

cma Complementary Medicines Australia

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In short:

- The failure of the regulators over many years to bring the industry into check continues to harm consumers.
  - Direct harm from poorly disclosed adverse events from complementary medicines and their interaction with conventional medicine.
  - Indirect harm, by consumers forgoing more evidence-based remedies (often to the detriment of their health) because they are sucked in by misleading and deceptive promotional hype. This also wastes their money which could be better spent.

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MMD Recommendations

Will they fix the mess?

- Thirty Eight
  - the NRA establishes the list of Permitted Indications, from which sponsors must exclusively draw, for listed medicinal products in the ARTG. √
- Thirty Nine
  - A new listing pathway (option 2) where the sponsor can provide evidence acceptable to the NRA to support the safety and efficacy of health claims that fall outside the list of Permitted Indications. √
- Forty Three
  - When a product is listed on the ARTG the sponsor is required to publish the evidence it holds to support the indications in the ARTG. √ **but industry oppose**

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MMD Recommendations

Will they fix the mess?

- Forty Four
  - where a medicinal product is listed in the ARTG under Option One (self-assessment), the sponsor is required to include a prominent disclaimer on all promotional materials to the effect that efficacy claims for the product have not been independently assessed and/or are based on traditional use. **√ but industry oppose**
- Forty Five
  - where a medicinal product is listed in the ARTG following an assessment by the NRA (0ption 2), the sponsor is able to indicate on all promotional materials and on the product label, that the efficacy of the product has been independently assessed for the approved indication(s). **√**

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MMD Recommendations

Will they fix the mess?

- Forty Nine
  - the NRA develops a more comprehensive post-market monitoring scheme for listed medicinal products. **√**
- Fifty Four
  - future requirements for advertising therapeutic products to the public are made consistent for all medicines and medical devices. **√**
- Fifty Five
  - the process of vetting and pre-approval of the advertising of therapeutic products to the public is stopped in favour of a more self-regulatory regime. **± very controversial**

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MMD Recommendations

Will they fix the mess?

- Fifty Six
  - that current mechanisms for managing complaints are disbanded and a new mechanism is established consistent with best practice principles for complaint handling. √
  - in establishing the new complaints management mechanism, a single agency should receive and manage all complaints on the advertising of therapeutic products to the public. √ **But who?**
- Fifty Seven
  - ~~consideration be given as to whether~~ the current range of investigation and enforcement powers should be broadened. √

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Conclusion

REGULATION AND SAFETY

Consumers Health Forum of Australia

Friends of Science in Medicine

Australian Skeptics

The Royal Australian College of General Practitioners

ABC The Checkout

- There is an urgent need for Minister Ley to respond to the Samson review and set in train long-delayed reform measures to protect vulnerable consumers from an often exploitative industry.
- There is danger that more "consultations" to flesh out broad-brush and controversial recommendations could delay implementation for years (as it has before).
- However, civil society organisations and the media will keep up the pressure on government.

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Further viewing: ABC Checkout

- TGA regulation
  - https://www.youtube.com/watch?v=_vPha4usTtI
- Swisse chlorophyll
  - https://www.youtube.com/watch?v=MTa_ccZBvEg
- Chronic pain: Nurofen
  - https://www.youtube.com/watch?v=tfNqBP900L8
- Pharma Sutra
  - https://www.youtube.com/watch?v=FTcLpY3MWPk
- Snot rocket science
  - https://www.youtube.com/watch?v=xyDZLvMhuSI
- A special welcome to the ABC's new commercial partner, Swisse
  - https://www.youtube.com/watch?v=c0WHvFI2I20

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