

Essential elements for effective regulation of therapeutic goods and services claims

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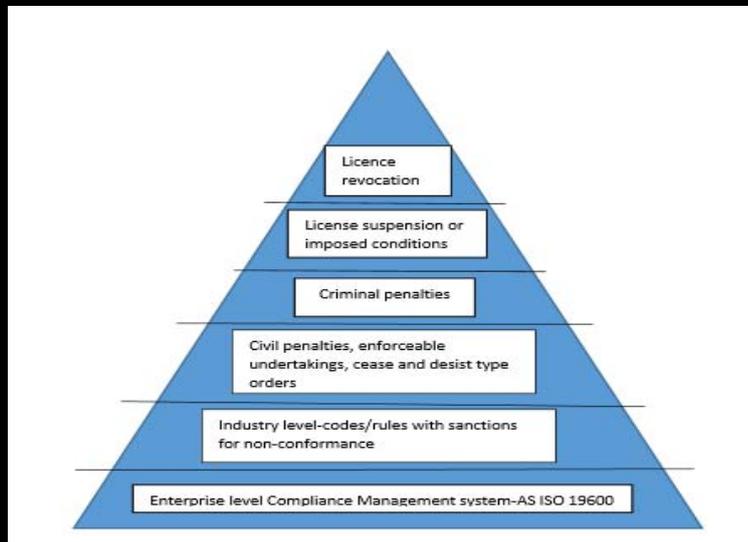
Seminar on Advertising of Therapeutic Goods and Services (and its Regulation)

Sydney, 17 March 2016

Cutting to the chase....this seminar is about..

- Consumers' health
- False & Misleading claims/rip-offs
- Need to send a strong message to the market that enterprises need to have an effective enterprise compliance system or take the consequence of **vigorous** and **timely** enforcement
- "It's Time"-for a new compliance regime for Therapeutic Goods claims
- "Seizing the Zeitgeist" – regulators need to be "innovative and agile" and who can be "disruptive" to scammers and shonky health claimers
- Self interest-Michael Porter indicated that countries with robust safety regulation and enforcement have a competitive advantage because consumers have more confidence in products from these countries (e.g. milk powder)
- Help Ken

The compliance pyramid



Drivers for compliance management system-why comply?

- Due Diligence Defence
- Reduction or elimination of negative exposure
- Reputation protection
- Losing money (lawyers fees, class action(e.g. Nurofen))
- Enhancing risk management systems

Bottom of the pyramid-enterprise compliance management system

- *Structural matters*

- Top management commitment
- Someone responsible for driving compliance
- Allocation of responsibility
- Management supervision
- A system of documentation of all compliance material
- Regulatory risk assessment and controls
- Compliance plan
- A system of documentation of all compliance material.

Bottom of the pyramid-enterprise compliance management system

- *Operational*

- Operating procedures (see Attachment B of FEMAG paper)
- Education and training
- Regular communications designed to secure compliance
- Access to expert advice

Bottom of the pyramid-enterprise compliance management system

- *Maintenance*
 - Monitoring systems
 - Reporting systems
 - Compliance failures identified, their causes analysed and rectification action taken

Next level up-codes of conduct

- *Structural matters*
 - Governing body commitment
 - Coverage
 - Consultation
 - Addressing consumer concerns
 - Adequate resources
 - Risk assessment
 - Allocation of responsibility
 - Appointment of a Compliance Officer/Manager
 - Compliance calendar/Compliance plan
 - A system of documentation of all compliance material
 - Complaints handling

Next level up-codes of conduct

- *Operational*

- Code administration
- Transparency
- Consumer awareness
- Industry awareness
- In house compliance including operating procedures
- Education and training
- Regular communications designed to secure compliance
- Sanctions and other powers for non-compliance
- Independent review of complaints handling decisions
- Data collection
- Performance appraisal

Next level up-codes of conduct

- *Maintenance*

- Monitoring
- Accountability
- Review

The third level tier of the pyramid-civil remedies

- **Essential requirements for compliance**

- *Stopping the conduct*
- *Access to compensation*
- *Demonstrated adequate levels of compliance*
- *Punishment for persistent and/or deliberate wrongdoing*
- *Innovative approach to regulatory action*
 - *TGA, AHPRA working with the ACCC- the ACCC being a regulator with stronger powers and a more assertive culture concerning consumer protection*
 - *Both organisations making therapeutic goods claims an enforcement priority*
 - *Using the most effective regulatory tool in each given circumstances (e.g. stopping the conduct quickly and seeking fines and giving such action publicity to send a clear message to the appropriate industry or profession)*

Stopping the conduct in a timely manner- Nurofen case

- Started in 2010 when the promotion of the Nurofen range of products “targeting” migraine, back pain, tension headache and period pain was awarded a CHOICE shonky award
- In June, 2011 Professor Paul Rolan put in a complaint to the CRP which was upheld but Reckitt Benckiser (Australia) Pty Ltd declined to comply.
- Dr Ken Harvey put in another complaint in 2012
- TGA “Regulation 9 order” followed in 2014
- Despite “assurances” given to the TGA the misleading promotion continued and in March 2015 the ACCC commenced legal proceedings which finally led to a determination in December 2015 and new pack labels in 2016 a few weeks ago
- In short, 6 years to get a result!
- Similar time frames with other cases eventually taken up by the ACCC such as Homeopathy Plus

Stopping the conduct in a timely manner-the solution

- The ACCC could:
 - First-see an injunction and a corrective advertisement immediately
 - Then seek penalties to send signals to the market (and make the bottom of the pyramid work)
- Professions regulators could:
 - Seek to stop offending conduct quickly (include having the power to refer to the ACCC where conduct is misleading and/or substantiation evidence required)
 - Establish fast track protocols with appropriate regulators in egregious cases and those requiring urgent action

The third level tier of the pyramid-civil remedies toolbox

- Civil pecuniary penalties
- Substantiation notices
- An injunction to stop conduct (a court order)
- Corrective advertising
- Compensation orders
- Enforceable undertakings
- Disqualification orders
- Infringement notices (penalty notice)
- Adverse publicity orders
- Safety warning notices
- Media releases
- Product liability and recalls provisions.

The third level tier of the pyramid-civil remedies

- The role of the bottom of the pyramid to work in this space was summed up succinctly by Justice Edelman found in *ACCC v Woolworths* when he stated that...“The penalties I have imposed are designed in broad terms to achieve specific *and general deterrence by requiring vigilance concerning quality management procedures to ensure the accuracy of representations and effective procedures for the recall or withdrawal of products and the notification of the ACCC. This is particularly so where products can affect consumer safety (emphasis added)* and the person deals in the sale of large volumes of consumer products”.

Top of the pyramid-criminal penalties and licence suspension or cancellation

- *Criminal penalties*-where breaches are deliberate or systemic. The maximum criminal and civil penalties (fines) for making false or misleading representations are \$1.1 million for businesses and \$220,000 for individuals.
- *Imposing conditions on, suspending or revoking a licence*-These actions can be applied where the regulatory system involves licensing and would again be available to the regulator to use where there has been a deliberate, systemic breach. Publicity about such action by the regulator sends a clear message to other in the industry to make sure that they have robust compliance management systems in place.

Cutting to the chase-time for action

1. Using a Therapeutic Claims Committee of Experts:
 - Triage role
 - Expert evidence provider
 - Reference point
2. Therapeutic good claims an enforcement priority for regulators (e.g. TGA, ACCC etc.) and closer liaison between regulators
3. Intelligent use of tools by regulators
 - Stop the conduct quickly first
 - Corrective advertising
 - Get fines later-need a deterrent impact
 - Promote the use of enterprise compliance management systems
 - Setting up an on-line monitoring team to constantly monitor websites and remove offending sites

Cutting to the chase-time for action

4. Holding a therapeutic goods and services claims scan day (ACCC already conducts scam watch days)
5. Support amendment of ACL to include a **general duty of safety**- this will drive
 - the development of safety compliance management systems at the enterprise level (see Justice Endelman's comments on slide 15)
 - Building safety into design of product
6. Capacity Building-ACCC providing leadership by including regulatory bodies including self regulatory bodies in its investigators course
7. Have a review seminar on this topic in 2017

References

- Copy of the paper downloadable from www.femag.org.au
- Copy of slides on www.medreach.com.au
- Any questions-compliance@ozemail.com.au