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Medicines and Medical Devices Review implementation

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TGA Health Safety Regulation

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Overview

Implementation of Expert Panel Review of Medicines and Medical Devices Regulation

- 58 Recommendations across multiple areas of medicines and medical devices.
- Extensive consultation such as discussion papers, submissions, interviews and workshops with key stakeholders
- Government accepted the majority of the Review recommendations, some with qualification.
- Review responses are policy decisions of Government – the TGA is charged with implementing that policy
- We are getting on with implementation…

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Complementary medicine reforms

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Overview - complementary medicine regulatory reforms

- Rec 35, 36 & 37 – publish a searchable catalogue of permitted ingredients and provide new methods for assessment of new ingredients.
- Rec 38 – develop a list of permitted indications for listed medicines.
- Rec 39 – create a new middle pathway for including complementary medicines in the ARTG following TGA pre-market assessment of efficacy.
- Rec 45 – allow sponsors to use a claimer on promotional material and medicine label where a product's efficacy has been assessed by the TGA.
- Rec 49 - more comprehensive post-market monitoring scheme for listed medicinal products.

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What does 'Permitted Indications' mean for sponsors?

- Sponsors listing a medicine in the ARTG will only be able to use indications from a list of **permitted indications.**
- Permitted indications will be '**low level indications**' that only refer to health maintenance, enhancement or self-treatable / self-manageable conditions .
- The '**free text**' field in the listed medicines application system will be removed.
- The TGA will be able to create a **non-permitted indications list** e.g. smoking cessation.
- Indications will not have to be '**word for word**' on the medicine label but the meaning and intent must be same.
- Sponsors will be able to apply for **additional indications.** The draft list of indications is now open on the TGA website for comment – closes **31 October 2017.**

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Who can use the new 'claimer' ?

- A claimer **can be used** by medicines that have had TGA pre-market assessment:
  - Complementary medicines assessed via the new pathway
  - Registered complementary medicines
- A claimer **cannot be used** by medicines that have **not had a pre-market assessment**:
  - Listed medicines, including those that have had a compliance review
  - "Grandfathered" medicines

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Therapeutic goods advertising to the public

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Advertising reforms – simplifying processes while strengthening compliance

- Rec 54 - **greater consistency** across regulation of advertising of different types of therapeutic goods
- Rec 55 - **ceasing pre-approval** of advertisements in favour of a more self-regulatory regime
- Rec 56 - implement a more transparent and efficient **complaints management process**
- Rec 57 - broaden & strengthen **investigation & enforcement powers**
- Rec 58 - **formal education program** for industry

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Advertising & Complaints – Implementing the recommendations

- Current process has significant issues – Highlighted in MMDR
- Government has set the operating parameters – Agreeing the MMDR

So….

- A generational opportunity to reshape the management of advertising & complaints…
- The details need to be worked through:
  - Bill changes
  - Code Changes
  - Regulations

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Changes to Advertising legislation:

- Changes to the Act are a key component of implementing the new advertising framework
- These changes will:
  - Provide a range of tools to support compliance with new requirements
  - Support the TGA as the single body handling complaints about advertising to the public
  - Remove the statutory requirements for pre-approval of advertisements
  - Improve regulatory consistency
- Transition arrangements allow for implementation of sanctions & penalties, new complaints handling processes & education program before pre-approval ceases (1 July 2018).

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Changes to Advertising legislation:

- A new definition of “advertise” – replacement of “advertisement”
- Definition makes it clear that it includes statements, pictorial representations or designs on the labels of products, in or on the packaging of the product; and on any material included with the product package, where they promote the use or supply of the goods
- Removal of media-based terminology – “broadcast” and “publish”

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Proposed improvements to the Therapeutic Goods Advertising Code

Advertising Code

- The Code is the core compliance standard for regulating the advertising of therapeutic goods to the public. All advertisements to the public must comply.
- The Code needs revision to support the advertising reforms
- Consultation on the Code opened 31 August and closes 13 October 2017. To be followed by consultation on a draft Code in early 2018

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What are the timeframes…

- A new Therapeutic Goods Advertising Code - by mid 2018
- Amended Regulations – commencing early 2018 with transitional arrangements
- Introduction of new complaints handling process managed by TGA – transition completed by 30 June 2018
- Procedures and Guidelines – progressive introduction throughout first half of 2018.
- Educational program - commencing early 2018
- New Governance mechanisms – Driving transparency and visibility - TBC
- A formal review in 3 years

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Some thoughts and Considerations…

- Secretary can instigate his own investigations…
- How should TGA triage complaints ?
- How do we ensure there is visibility and transparency in our processes …
- Mechanisms to listen and understand stakeholder views and perspectives…
- Working relationships with other regulators…
- Governance Forums

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Compliance and enforcement

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Consultation: TGA – enhancing sanctions and penalties in the *Therapeutic Goods Act 1989*

Version 1.0, May 2017

TGA Health Safety Regulation

Review Recommendation 28 (in part)

- *The Act should be re-drafted to **provide for graduated penalties** that allow TGA to respond appropriately to the full range of non-compliance from repeated minor breaches through to serious non-compliance*

Review Recommendation 57 (in part)

- *Consideration be given as to whether **the current range of investigation and enforcement powers should be broadened***

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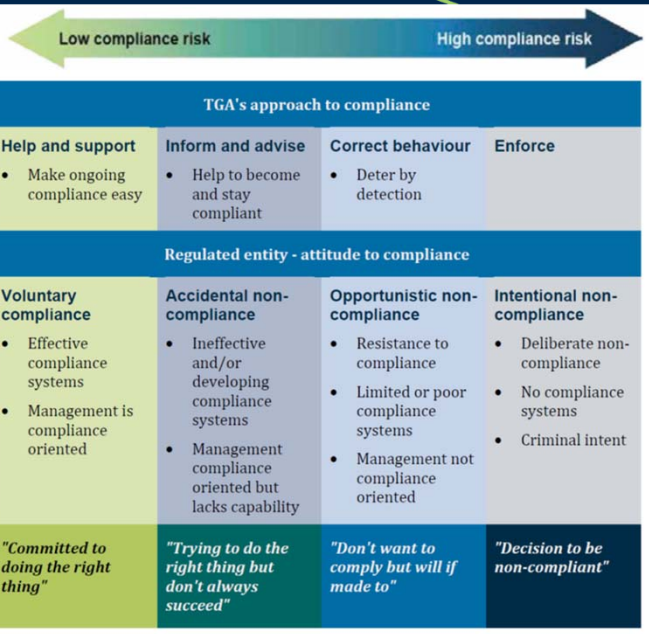

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Other possible actions & sanctions

- **Product suspension/cancellation**
- **Directives** to amend/remove non-compliant advertising
- **Infringement notices -** 12 penalty units for an individual, 60 penalty units for a body corporate
- **Civil penalties** with reduced burden of proof but significant financial penalties
- **Ability to seek an injunction** to address serious non-compliance
- **Ability to issue substantiation notices** requiring information to substantiate claims made in an advertisement
- **Ability to issue public warning notices** where we suspect that an advertisement for therapeutic goods may contravene the Act and we are satisfied that people have suffered or likely to suffer, and it is in the public interest to issue the notice

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Conclusions

- Currently implementing the most sweeping changes in 25 years
- MMDR recommendations took a range of stakeholder views into consideration – this has set the framework…
- Decisions about the specific policy changes are up to the Minister…
- Significant opportunity for us to work together to shape this reform
- The TGA will work with stakeholders to develop the best possible framework – more consultations & activities ahead….

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