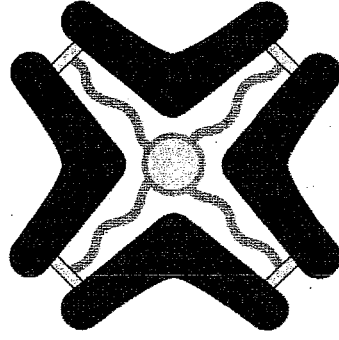


Designing a Regulatory Framework for the 21st Century Consumer

Dr Deon Schoombie ASMI



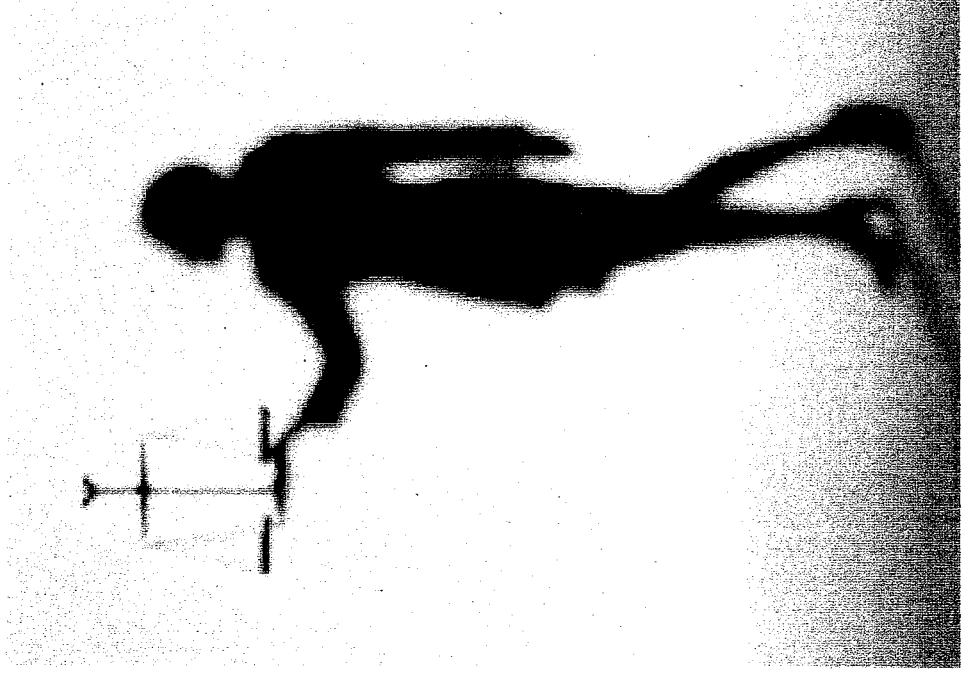
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Reform Principles



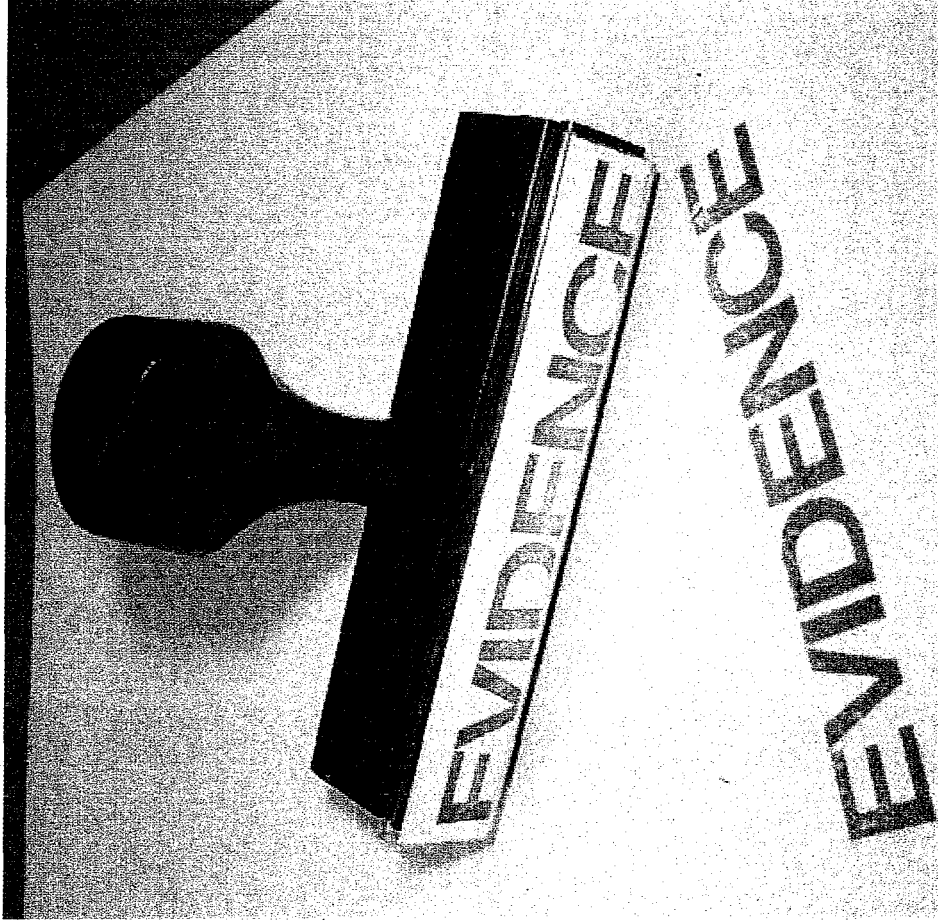
Balancing Risk vs Benefit for the consumer



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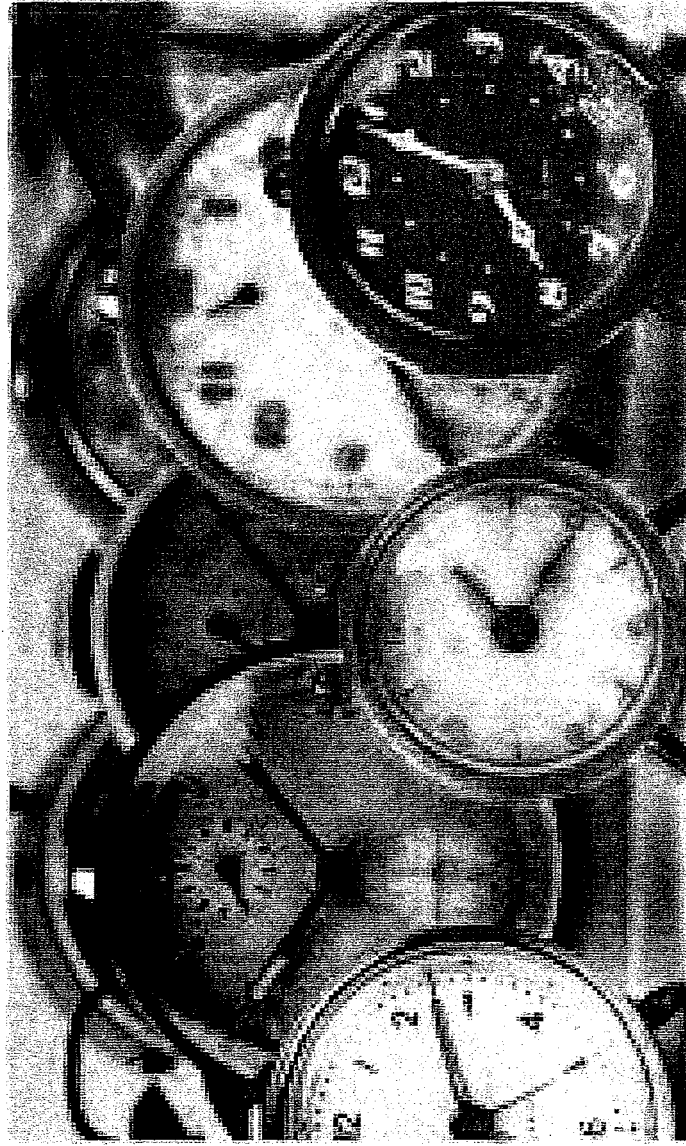
Evidence-based approach



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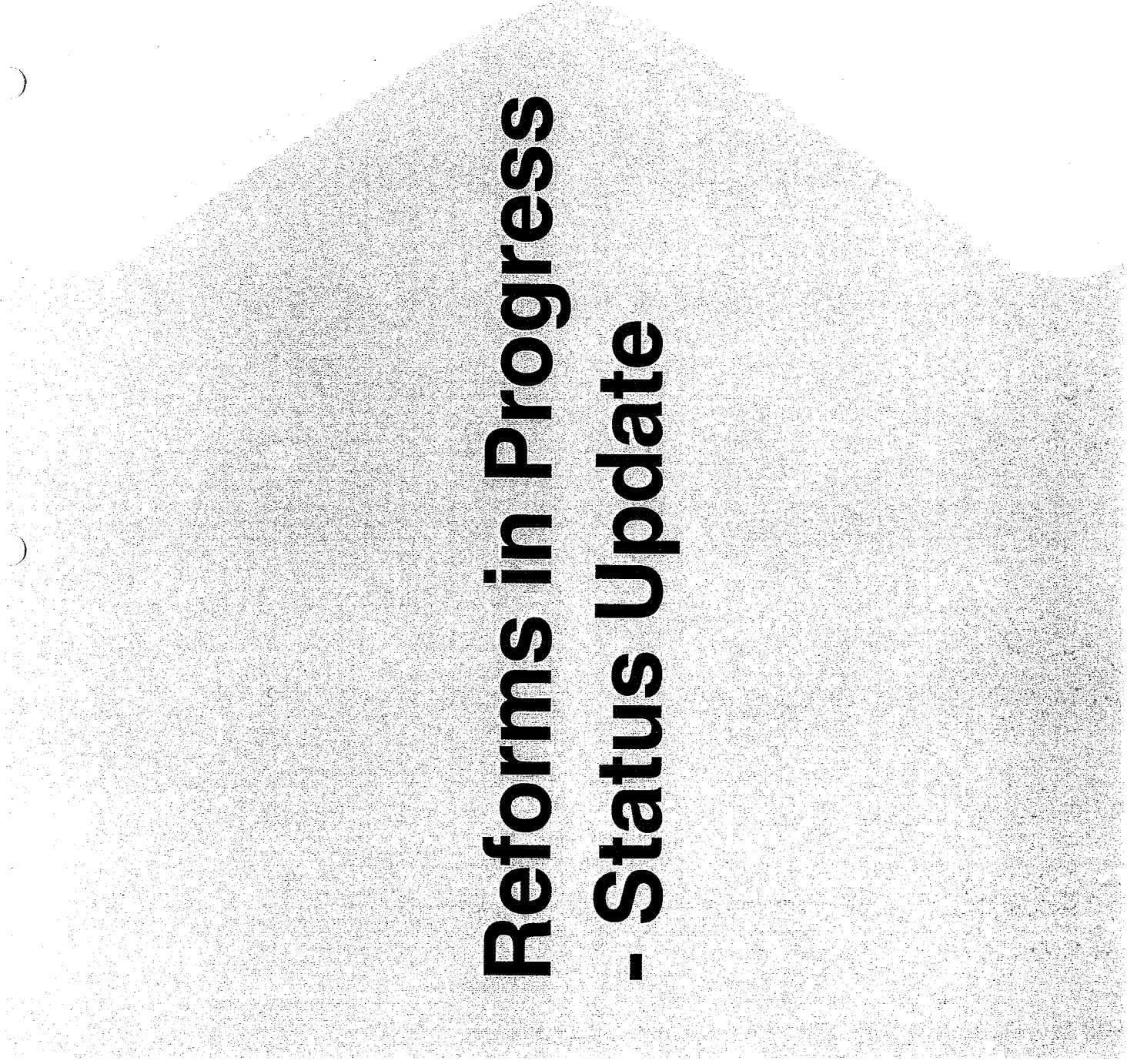
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Adequate Transition Time



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Reforms in Progress

- Status Update

Reform Area: Labelling & Packaging

STATUS UPDATE:

- Consultation on draft TGO closed July 2013
- Awaiting final round of consultation - RIS

ISSUES TO RESOLVE

- Balance between size of brand and active
- Flexibility to accommodate different types of packs
- Acknowledge value of logo's/graphics to aid consumer selection
- Pragmatic transition window
- Umbrella branding where appropriate



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Reform Area: Advertising

STATUS UPDATE:

- Consultation closed July 2013
- Awaiting Government response

ISSUES TO RESOLVE

- Single point for pre-approvals
- Timely complaints handling
- Proper penalties & sanctions
- Harmonisation with NZ (ANZTPA)



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Reform Area: Complementary Medicines*

*Levels of Evidence Guidelines & Coded indications/free text

STATUS UPDATE:

- Consultation closed March 2013
- Awaiting TGA response

ISSUES TO RESOLVE

- Clear and reasonable evidence requirements
- Clear distinction of claims – “purpose of use” vs “advertising”
- Standardised claims (coded indications) – abolish free text
- Efficient mechanism to introduce new indications
- Retain existing indications unless safety issue can be demonstrated
- Effective post market enforcement



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Reform Area: Scheduling

STATUS UPDATE:

- Consultation closed April 2013
- Advisory Committee recommendation awaited

ISSUES TO RESOLVE

- Inconsistency in scheduling decision making
- Risk aversion to Rx to OTC switch
- Risk aversion to S3 advertising
- Inconsistency with NZ (ANZTPA)
- Adoption of proposed S3 communication model – balances informed consumer with empowered pharmacist



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Reform Area: Business Process Review (BPR)

STATUS UPDATE:

- Implementation of reforms commenced April 2013
- Monitoring implementation & further refinements

ISSUES TO RESOLVE

- Commitment to transparent process
- True reform lacking with complex applications
- Timelines biased in favour of regulator
- Issues surrounding umbrella branding require further attention
- Value of monograph system?
- Loss of “notifications” unacceptable



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Reform Area: ANZTPA

STATUS UPDATE:

- Australian OTC BPR review completed – implementation underway
- DAEN & SARA completed
- Awaiting TGA response to consultation on legal framework - Rules
- New agency to open doors in 2016

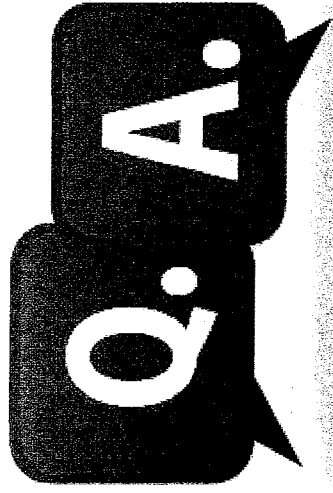
ISSUES TO RESOLVE

- Extent of harmonisation and potential “opt-out” provisions
- Limited transparency of detail to date
- Advertising & Scheduling - Reconciling differences in each market
- Possible derailers - Legal challenges in each country
- Early communication with industry critical
- Transition arrangements and impact on industry



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Q&A with TGA

MC – Virginia Trioli
&

Prof. John Skeritt National Manager - TGA



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