



Australian Government
Department of Health
Therapeutic Goods Administration

Regulatory Reform - an update

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ASMI Annual Conference

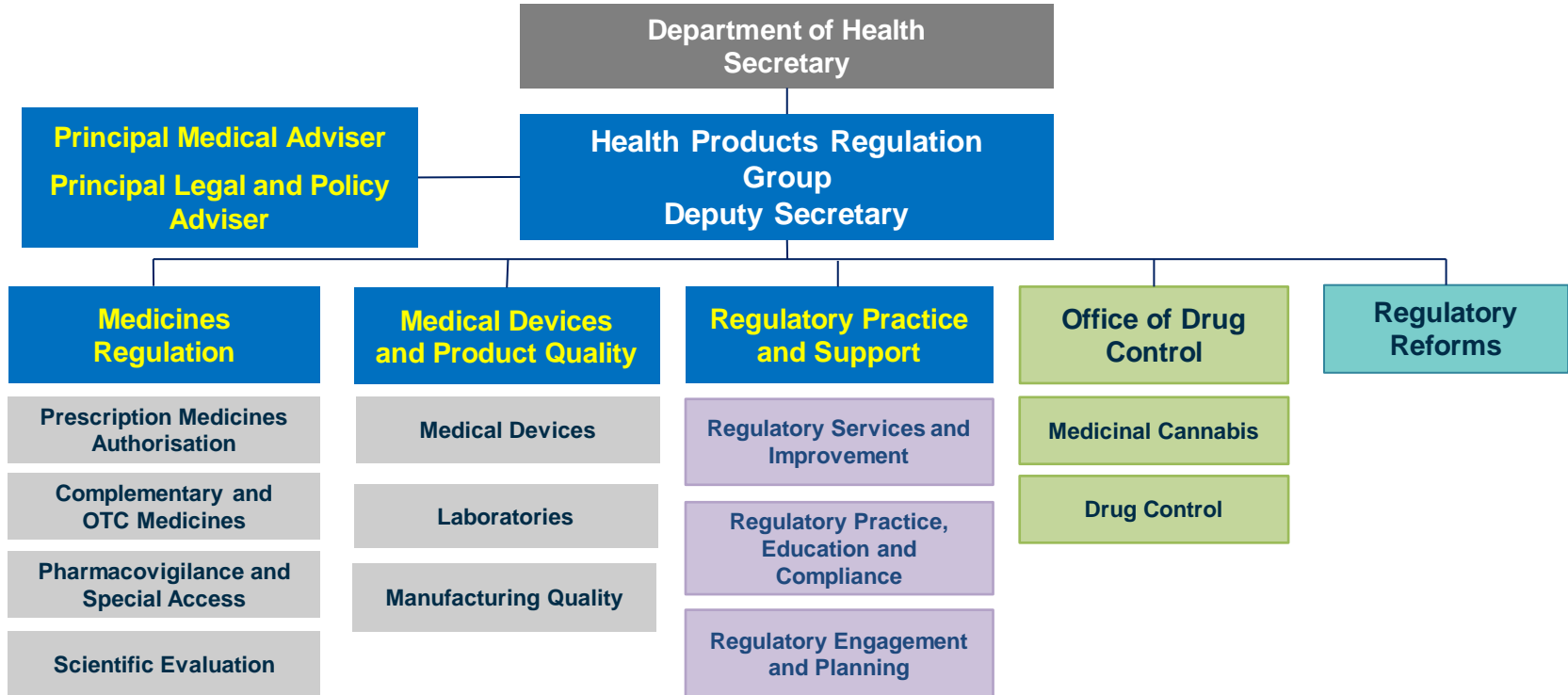
27 October 2016

TGA Health Safety
Regulation

This presentation

- **New Health Products Regulation Group**
- **Business as usual - performance statistics for 2015/16**
- **TGA stakeholder survey**
- **Medicine labelling changes**
- **Medicines and Medical Devices Regulation Review**
- **Next steps**

Health Products Regulation Group structure



Complementary medicine business reforms

- **Electronic applications system** for registered complementary medicines
- **Five registered complementary medicine categories** based on availability of quality, safety and efficacy data
- **Single legislative source of information** for about 5000 permitted ingredients
- **Updated evidence guidelines** for listed complementary medicines
- **Strong international cooperation on CM ingredient safety** (Sin/Can/Switz)
 - Common assessment template and approach to ADI calculations and minimum data requirements
 - Move to a common evaluation process, but individual regulators will make sovereign decisions to approve or reject applications

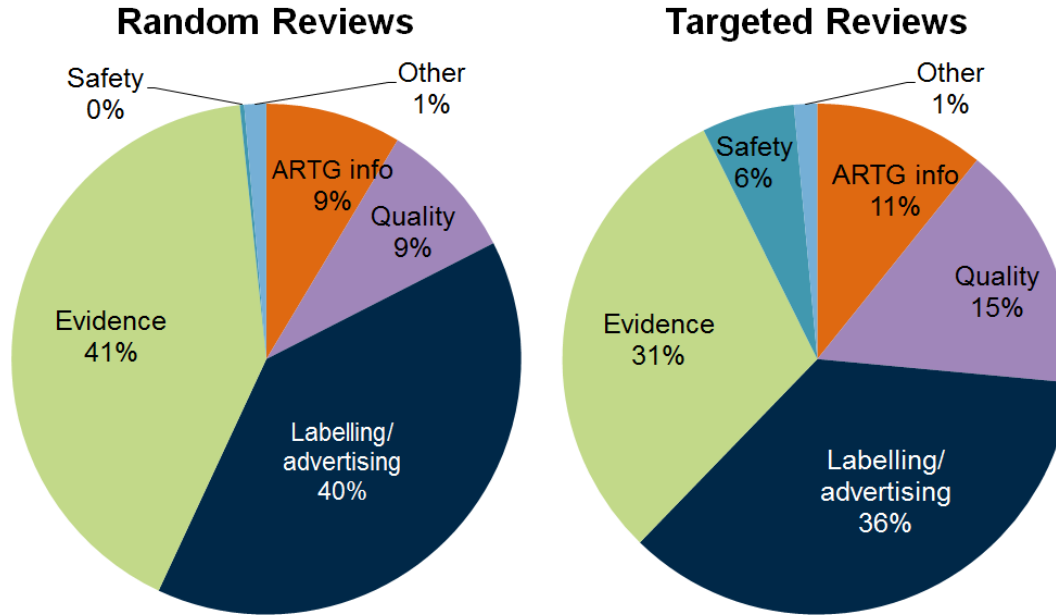
2015-16 TGA Performance statistics: complementary medicines

	2014-15	2015-16
New listed medicines	1879	1644
New listed medicine ingredients approved	5	18
New registered medicines approved	4	2
Registered medicines variations approved	28	27

Compliance problems: complementary medicines

- **The number of compliance reviews more than doubled**, based on:
 - complaints and referrals from internal and external stakeholders
 - screening of recently-listed medicines
 - assessment of some products that are not listed on the ARTG
- **80% of medicines had compliance breaches** in 2015-16 (vs 73% for 2014-15)
 - Labelling, advertising and evidence are still the major compliance breaches
 - 3 products were found to have ingredient safety related issues in 2015-16
- **Information of each product is that cancelled** published at www.tga.gov.au/complementary-medicines-cancellations-artg

Outcomes of completed reviews



Actions taken following listed medicine reviews

Actions following a Request for Information	
Medicines found to be compliant	81
Proposal to cancel notice sent by TGA	327
Total	408
Actions following a Proposal to Cancel notice (327 medicines total)	
Medicines cancelled by TGA	44
Medicines cancelled by sponsors	76
Compliance breaches were addressed	207

OTC medicine approvals 2015-16 vs 2014-15

- The number of new OTC applications was lower due to fewer low risk (N1) applications
- **Approval times** for most application types consistent
- **Significant increase** in approval times for N3 ('generic' medicine) and C4 (non-quality change) applications, due to application complexity

Application type	Number completed	Median	Target time (days)	% within target
New medicines				
N1	79	14	45	100
N2	3	26	55	100
N3	25	90	150	100
N4	50	89	170	100
N5	6	151	210	83
Change applications				
C1	618	5	20	97
C2	309	8	64	99
C3	4	31	120	100
C4	12	110	170	100

Medicines labels – why change ?

- Label requirements **had not been updated for over 15 years** and are **not aligned with international practices**
- **Current labelling can lead to poor medicines use/safety concerns:**
 - Lack of awareness of the active ingredients, possibility of accidental overdose when taking multiple medicines as well as dispensing errors
 - Poor readability of medicine labels
 - Difficulties in following directions for use or identifying advisory statements
 - Potential for use of the wrong medicine - similarities in medicine branding
- **Four year transition period from 31 Aug 2016**, minimising cost to industry, aligning with ingredient name changes and rolling out education programs

Main changes for OTC medicines include:

- **Larger text size for names and quantities of active ingredients** in registered medicines
- A **minimum text size of 3.0 mm** (smaller font sizes for medicines with >4 active ingredients, medium (25-60 mL) and small (<25 mL) containers)
- **The name of the medicine must be in a continuous uninterrupted manner**
- **Information required to be on a label** must be in colours that contrast strongly with the background (batch number and expiry date can be embossed)



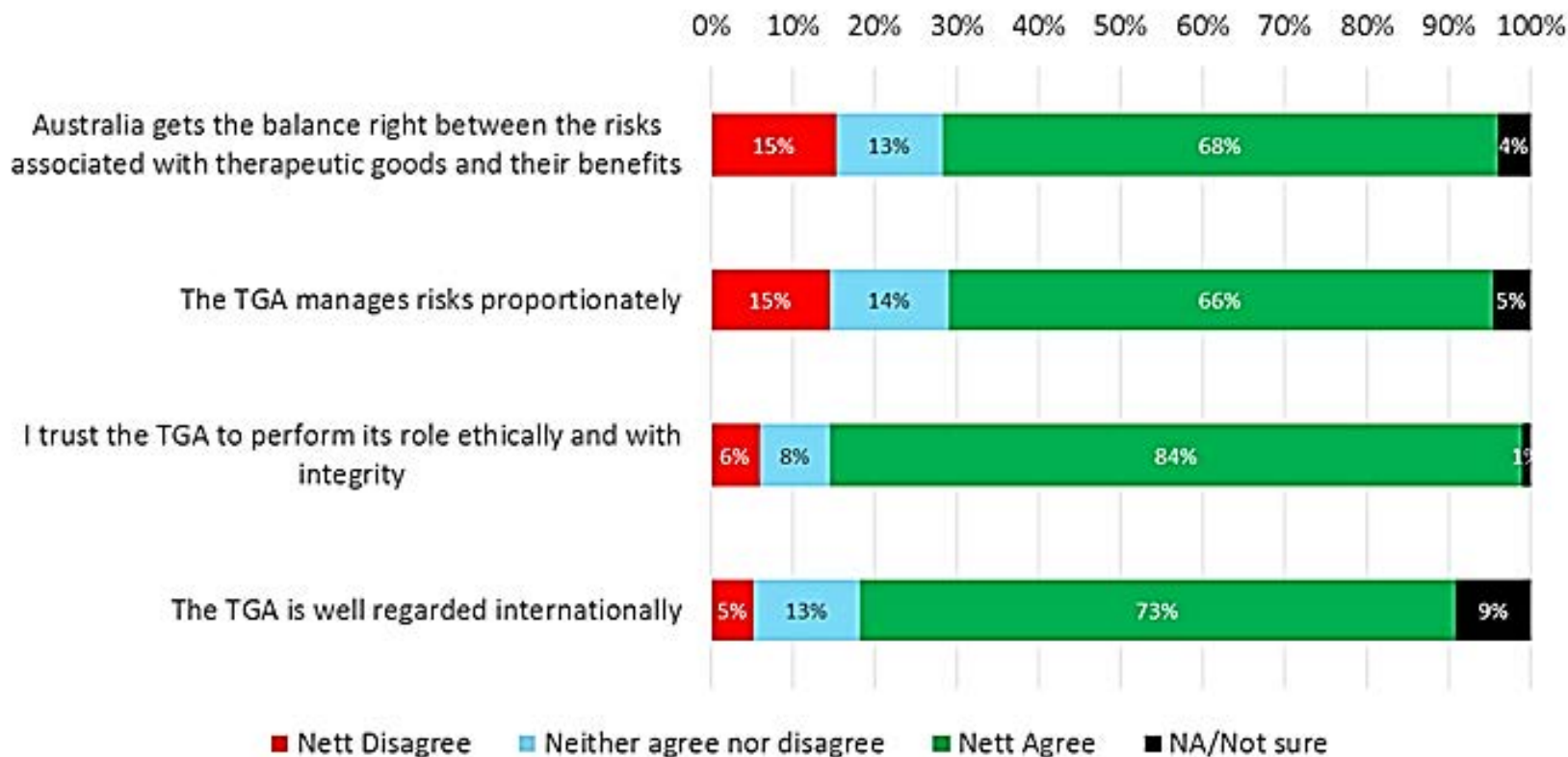
Main changes for OTC medicines include:

- The number of substances such as allergens that must be declared has increased (e.g. to include crustacea, fish, egg, soya, milk, tree nuts)
- Most **registered OTC medicines** will require a table on their packaging that provides critical health information in a consistent manner
- **permit the use of an active moiety only** when the full approved name is included in the 'critical health information' table
- Sponsors can use either the 'old' or 'new' rules until **31 Aug 2020**

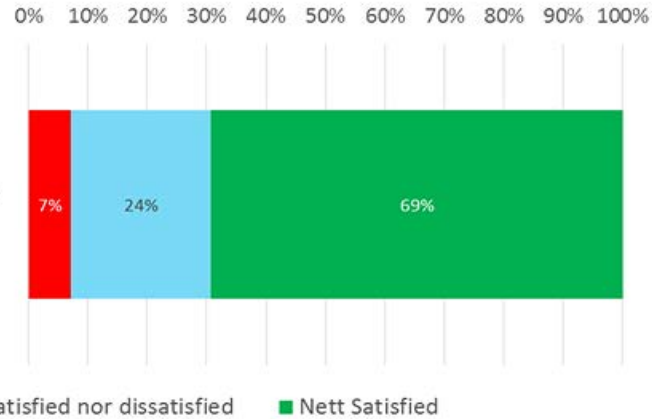


TGA stakeholder survey 2016

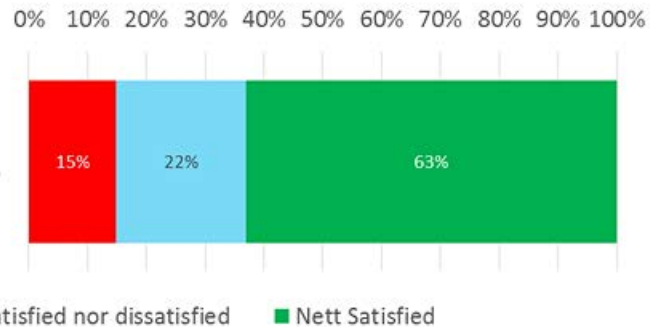
- A requirement for the Government's **Regulator Performance Framework**
- **2810 responses:** 449 health professionals, 65 consumers, 1628 from industry
- Results remarkably positive in terms of **trust and confidence in the regulator**
 - 79% of industry have high/very high confidence in TGA safeguards
 - 61% of community/ consumer groups with 27 % ambivalent/ unsure
- **Users satisfied or very satisfied** with TGA consultations (63%), exhibitions (75%) and information sessions (82%) respectively.
- Main area for work is to **TGA to engage more actively with consumers**
 - They are aware of, and have a generally favourable perception of the TGA, but many unsure
 - Consumers also felt least engaged in TGA policy consultations



How satisfied are you with the TGA information website?



Overall, how satisfied are you with the experience of COMMUNICATING with the TGA?



Review of Medicines & Medical Devices Regulation

- **Expert Panel** commenced late 2014 after most of 2014 in pre-work
- **Review process** included discussion papers, submissions and interviews by the panel
- **Two reports** on medicines and devices and complementary medicines and advertising released during 2015 with 58 recommendations
- Following release of the reports, workshops held with key stakeholders by the Department to get **feedback on recommendations**
- Minister Ley took preferred position to Cabinet
- **Government response** was publicly released on 15 September 2016

Key principles endorsed by Government

- **The Australian Government retain responsibility for approval of therapeutic goods** rather than automatically accepting international approvals, but TGA needs to:
 - make greater use of overseas evaluations
 - introduce greater flexibility in approval pathways for both medicines and medical devices
 - more appropriately align level regulation with the actual risk posed by certain types of products
- **The review did not cover** cell, tissue and blood regulation, clinical trials nor aspects of TGA's governance or structure

Seven bundles of work agreed and costed

1. Increasing Flexibility for Registration and Post-Market Processes for **Medicines**
2. Increasing Flexibility for Approval and Enhanced Post-Market Monitoring of **Medical Devices**
3. Increasing Flexibility for Pre-Market Approval and Increased Evidence of Efficacy of **Complementary Medicines** for Consumers
4. Simplified and More Effective Regulation of **Advertising**
5. Streamlined Regulation of **Patient Access** to Therapeutic Products
6. **Further Reviews**
7. Rationalisation of **TGA Statutory Advisory Committees**

Complementary medicines changes

1. Streamline **transparency and predictability** of regulation:

- Better regulatory guidance materials
- Catalogue of approved ingredients
- Introduce permitted indications for Complementary Medicines
- Adopt/ develop evidence monographs
- Right of review for applicant of TGA decisions on ingredients
- Establish ingredient assessment timeframes
- Continue stakeholder input through an advisory committee

Complementary medicines changes

2. Increasing the **transparency of evidence of efficacy** for particular indications

- Sponsors encouraged but not mandated to publish efficacy evidence
- Greater education on what AUST-L means, but sponsors not required to publish a label disclaimer
- A new class of complementary medicines with efficacy assessed by TGA prior to market authorisation. Sponsors allowed to make higher-level claims than listed CMs.
- Closer linkage to advertising claims

3. More **use of overseas assessments** for new ingredients

Complementary medicines changes

4. Increased **post-market monitoring and compliance**

- More products to be subject to random and targeted post-market review
- Timely information on products subject to post-market review
- Recommendation that TGA is able to refuse to list particular products
 - Intent able to be achieved through current mechanisms
 - i.e. allowing CMs to contain only permitted ingredients and targeted reviews by TGA of products immediately post-listing

5. Improving the competitiveness of the complementary medicines industry by providing **incentives for innovation**

- Could include consideration of data protection
- Also use of new “listed-plus” pathway

OTC medicine changes

- **No changes to the OTC evaluation framework** as successful business process reforms in 2012 and reduced evaluation times
- **Notification of many variations by sponsors to TGA rather than requiring evaluation** where the variation does not impact quality, safety or efficacy of the product
- **Enhanced electronic reporting** of adverse events and **enhanced information-sharing** with overseas regulators



Further reviews to be undertaken

- **In scope**
 - Medicines **Scheduling Policy Framework**
 - **Schedule 3 medicine advertising** guidelines
 - Review regulation of lower-risk medicines
- **Proposed process**
 - Document the basis of current approaches, approach of other regulators, and alternative frameworks
 - Conduct stakeholder workshops
 - Consultation papers and formal feedback on options
 - Provide advice to Minister on options
 - Ministerial decision, change to regulations?



Scheduling policy framework

Regulation 52E Secretary to take certain matters into account in exercising powers

- (1) In exercising a power under subsection 52D(2), the Secretary must take the following matters into account (where relevant):
 - (a) the **risks and benefits** of the use of a substance
 - (b) the **purposes for which a substance is to be used** and the extent of use of a substance
 - (c) the **toxicity** of a substance
 - (d) the **dosage, formulation, labelling, packaging and presentation** of a substance
 - (e) the **potential for abuse** of a substance
 - (f) any other matters that the Secretary considers **necessary to protect public health.**

SPF - considerations for reform

- **Risk-benefit balance**
 - Is there an excessive focus on risk?
 - Are the scheduling decision criteria appropriate?
 - Would a formal risk-benefit framework assist in decision making?
- **Decision-making transparency**
 - Clarify requirements for scheduling submissions?
 - Publish applications (or a summary)?
 - Publish committee deliberations?
- **Decision-making principles**
 - Clarify the cascading principles?
 - Clearer policy framework around unscheduled medicines?
 - Consider impacts of scheduling decisions on the wider health-system?

SPF - considerations for reform

- **Information availability and input to decision-making**
- **Governance**
 - A forum for oversight of the SPF?
 - Enable scheduling decisions to be reviewed?
- **Business processes**
 - Streamline timeframes and reduce rigidity?
 - Parallel registration and rescheduling proposals?
 - Rescheduling of classes of products?
 - Develop a process for identification of rescheduling candidates?
- **Incentives for rescheduling**
 - Provide limited market exclusivity for products with the rescheduled substance?

S3 (pharmacist only) medicines advertising

- Currently **only a limited number of S3 medicines can be advertised**
- **The Expert Panel found very diverse views** on possible change
 - And whether the current situation led to unnecessary GP visits
- **Government** has asked for more specific consultation to be conducted
- **Options canvassed by stakeholders** in 2015 workshops, included:
 - Make no change to the current system
 - Move instead to having a small list of substances forbidden from advertising
 - Move to a self-regulatory approach
 - Review overseas practices and experience
 - Allow ‘information provision’ by industry but not advertising

Further reviews: low risk products

Recommendation Fourteen

The Panel recommends that the Australian Government undertake a review of the range of products currently listed in the ARTG (not including complementary medicines) and subject to regulation under the medicines framework, with a view to ensuring that:

1. Products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act; and
2. Goods remaining under the auspices of the Act are subject to regulatory requirements that are commensurate with the risk posed by the regulated products.

Further reviews: low risk products

Recommendation Twenty-three

The Panel recommends that the Australian Government undertake a review of the range of products currently classified as Class I medical devices, with a view to reclassifying products as consumer goods in circumstances where the product poses little or no risk to consumers should it not perform as specified or malfunctions.

Recommendation Forty-eight

The Panel recommends that the Australian Government undertakes a review of the range of complementary medicinal products, currently listed in the ARTG and subject to regulation under the medicines framework, with a view to ensuring that products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act.

Next steps: identify product types in scope

- Water-soluble vitamins and minerals, homeopathic products?
- Medicated lozenges
- Primary and secondary sunscreens
- Disinfectants, medicated soaps and toothpastes, nappy rash treatments
- Some class one medical devices
- Sanitary tampons
- Other products?

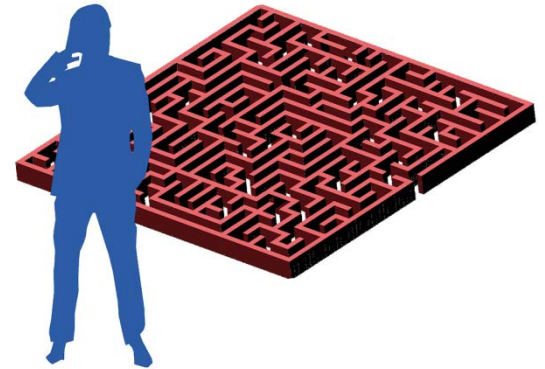


Next steps: develop a risk framework

- For medicinal products, **this could include parameters** such as:
 - safety of the ingredients
 - route of administration
 - risk associated with the claims including labelled use
 - nature of the condition being treated/ prevented
 - nature and number of the population using the product
 - impact of poor manufacturing quality on safety/efficacy
- **Regulatory ‘familiarity’** does this reduce uncertainty or actual risks?
- What is the ability of sponsors to **objectively self-assess** the product?
- Look at **international experience/alternative regulatory approaches**

SME regulatory assistance and clearer regulatory guidance

- Aim is to help small business navigate the 'regulatory maze' through advice, guidance documents and workshops
- Builds on work by **TGA Regulatory Assistance Team** over recent years
- **Would not replace** detailed product-specific advice provided by regulatory consultants



Other Recommendations

- **Deferred: Comprehensive review** of the Therapeutic Goods Act and Regulations
- **Deferred: The Government review and enhance TGA's funding**
- **Not accepted: Chief Medical Officer to become decision maker** (rather than TGA delegate) for all medicine and device decisions
- **Maintained: Complementary medicines advisory committee**

Advertising of therapeutic goods

- **Public advertising of therapeutic goods continues to be regulated by TGA** under a framework which includes an advertising code
- **Abolish mandatory pre-approvals of advertising**, and move to a self-regulatory regime – will need strong and timely compliance powers
- **New mechanism for managing complaints** managed in a streamlined process through a single agency
- **Investigation and enforcement powers** to be broadened
- TGA to run **sponsor education programs** to assist in compliance

How will we pay for the reforms?

- **Government agreed that we could use TGA reserves** (and 2015/16 surplus) to pay for cost of design of reforms and implementation of new systems
- **Separately** a systematic evaluation of appropriate fees and charges will be needed:
 - For new (e.g. enhanced comp meds compliance) and existing activities
 - So fees and charges may change



A great opportunity to implement important reforms ... but must avoid diverting resources from 'business as usual' regulatory work



Implementation and Governance

- **A broad plan for implementation of reforms over the next 18-24 months** has been agreed by Government
- **Project teams** have been established at TGA around each priority area
- **Some consultations will be targeted** (e.g. regulatory business processes) while **public consultations** will be held on areas of broader public health interest
- **We will soon publish a timetable for the initial group of stakeholder consultations**

Next steps

- **Where specific recommendations have been accepted by government**
 - **TGA has been empowered to propose much of the detail** on how specific changes could be implemented – ‘the how’
 - **We will consult with stakeholders** in developing the detail on implementation, including assessment of regulatory impacts and fees and charges
- **Where further reviews were agreed** (i.e. Scheduling Policy Framework, S3 advertising, low risk therapeutic goods, who manages advertising complaints)
 - Options papers will be developed and stakeholder workshops to be held
- **We will need to go back to government for final decisions**, in particular on the further reviews and where changes to the Act/Regulations are needed



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