Background

• 2013 Productivity Commission report highlighted that small to medium enterprises (SMEs) face challenges in navigating regulatory frameworks.

• National Innovation and Science Agenda - need to boost the SME subsector in Australia.

• The regulatory process is often neglected by innovators until very late in the product development cycle.

• We need to make the regulation process more easy to understand, and provide better support services for SMEs……but to not replace the role of regulatory consultants.
The regulatory framework is complex

• *Therapeutic Goods Act 1989* of 649 pages
• *Therapeutic Goods Regulations 1990* of 278 pages
• *Therapeutic Goods Medical Devices Regulations 2002* of 187 pages

• And there are also .....  
  – Charges Acts  
  – Customs (Prohibited Imports) regulations  
  – Dozens of legislative instruments  
  – All written in legalese
Development of SME Assist

- **Consultations** undertaken in 2016 with industry organisations, government departments, MTP Connect and in the margins of workshops and conferences
- Explored international regulatory support (FDA, EMA) models
- Also “signposting” to other support
- **Launched in June 2017** by Minister Hunt
  - Targets the needs of SMEs
  - Informs therapeutics R&D groups
  - Assists them to meet requirements for local and international markets
Six components

1) SME-specific guidance

Covers a range of introductory topics, such as:
- Basics of regulation
- Market authorisation
- When to engage with the TGA
- Medical devices overview
- Useful resources

Written in plain English and targeted at SMEs and R&D organisations that have not previously interacted with the TGA
2) Education and training

- Videos and presentations
- Workshops
  - *Meeting Your Obligations*: workshops in Melbourne (Aug) and Sydney (Nov)
  - Collaboration with the Dept of Industry’s Entrepreneurs’ Program
  - Included an overview of medicine regulation, case study examples, Q&A with a panel of experts, and topic-specific breakout sessions
  - Medical Devices Sponsor Information Day targeting the needs of SMEs (Oct)
3) Interactive tools

- **Decision trees** to better understand the regulation of specific products
  - Is my product a therapeutic good?
  - What classification is my medical device?
4) Phone/email support

- To provide more tailored and efficient assistance to SMEs

- A massive number of requests are received by TGA annually
  
  e.g. from July 16 to June 17:
  - 20,720 phone call requests
  - 7,957 email requests
  
  ..... about 120 enquiries a day!
5) Improved data capture

- **Subscription service** to keep SMEs up to date
- **Better identifies SMEs** and helps direct their enquiries
- **Ongoing investigations** into how we can deliver more tailored assistance to SMEs
6) Signposting to other services

www.tga.gov.au/sme-assist/useful-resources-business

- Business support from international regulators
- Funding opportunities
- Access to research facilities and training
- Tools and support for business
- Subsidy and reimbursement
- Upcoming events relevant to business
In the first 5 months:

- **17130** visits to the SME Assist web page
- **259** subscribers, of which 85% are small and medium businesses
- **2079** users of the decision tree tools
- **300** attendees at workshops
Regulatory Guidance development

- Help explain the Therapeutic Goods Act and Regulations to assist industry to understand how to apply them to their product/s
- In both web-navigable and PDF styles

Recent examples:
- Special Access Scheme and Authorised Prescriber
- Pre-submission meetings with TGA
- Manufacturing licences and GMP certification
- Medicine minor variations
- Priority review of prescription medicines
- Pharmacovigilance requirements
- Registered complementary medicines
- Recall Procedures
Upcoming Guidance documents

**Australian clinical trials handbook**

**Adverse events reporting**

**Medicines scheduling**

**Therapeutic Goods Advertising**

**Release of products for supply**

**Guidelines for biologicals**

**Prescription medicines**
- Provisional approval pathways
- Using reports from overseas regulators

**Complementary medicines**
- Permitted indications
- Permissible ingredients
- New ingredient assessments
- Postmarket monitoring
- Efficacy monographs
- Variations
- New pathways

**Medical Devices**
- Accelerated assessment
- Use of overseas regulatory approvals
Coming in early 2018

Additional workshops and webinars
• Meeting Your Obligations – more sessions
• Advertising and making therapeutic claims
• Regulation of biologicals
• Manufacturing requirements
• Medical Devices

Drop-in Days
• Sessions where SMEs will get 1:1 time with TGA experts
Coming in early 2018

Researcher – specific guidances
• Researcher considerations in product discovery and research design
• Clinical Trials Decision Tree (CTN vs. CTX)

Medicines and Medical Devices Review
• Means that all areas of the regulatory framework are undergoing major changes
• So their explanation is even more important