



Australian Government

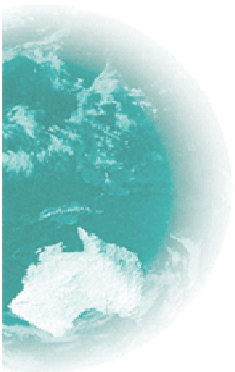
Department of Health and Ageing  
Therapeutic Goods Administration

# USE OF ICH GUIDELINES IN PRESCRIPTION MEDICINE REGULATION IN AUSTRALIA

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Office of Prescription Medicines

TGA





# National Medicines Policy

Quality, safety  
and efficacy

TGA

2 Equity of access

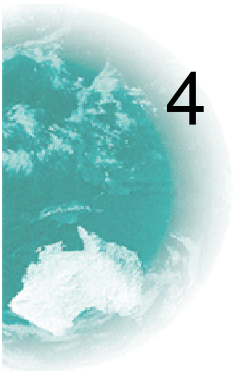
Pharmaceutical benefits

3 Viable industry  
support

Government

4 Quality of  
use of medicines

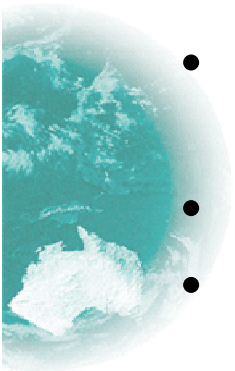
Pharmaceutical  
education programs





# What TGA does

- Sets quality standards
- Maintains register of Therapeutic Goods
- Evaluates quality, safety and efficacy
- Audits and licences manufacturers
- Tests complaint samples
- Tests random samples
- Conducts voluntary ADR and Device Incident reporting scheme
- Controls access to unregistered medicines & devices
- Regulates advertising and claims

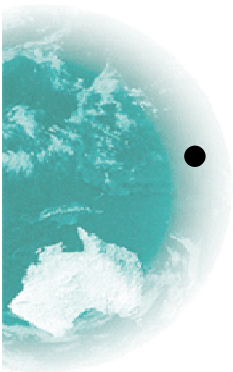




# Risk based assessment

Level of assessment is based on risk of the product, so:-

- Registrable or high risk products are assessed for quality, safety and efficacy
- Prescription medicines are high risk medicines





# ICH use in Australia

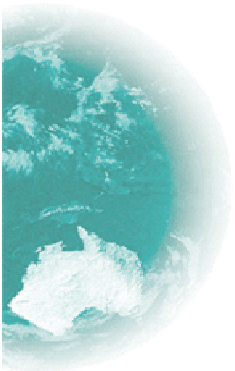
1991-Baume Review into medicine regulation recommended that there be no unique Australian guidelines or requirements, unless justified on public health grounds. Baume recommended that the TGA should use globally harmonised guidelines and standards. Since then TGA has used European versions of ICH guidelines almost exclusively





# Data requirements

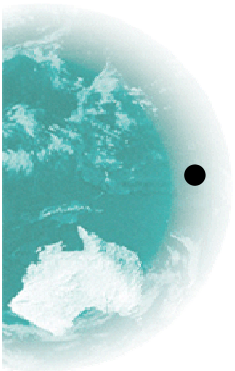
- Are based on European/ICH requirements
- TGA accepts submissions in CTD format (mandated via legislation)
- For prescription medicines, TGA has a policy of adopting internationally agreed guidelines wherever possible, especially ICH guidelines, and does this through a process of:
  - Internal Review
  - Consultation with External Stakeholders, and
  - Publication of Outcomes





# Use of Guidelines

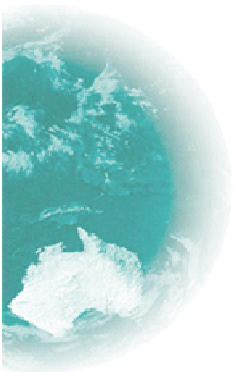
- Guidelines are not legally enforceable requirements
- Guidelines set out best practice in demonstrating quality, safety and efficacy at the time they are written
- Not intended to replace careful consideration of the medical science





# Timeframes

- Evaluation timeframes are imposed by legislation for high risk registrable medicines, and
- TGA suffers a 25% loss of evaluation fees if decisions not made in time





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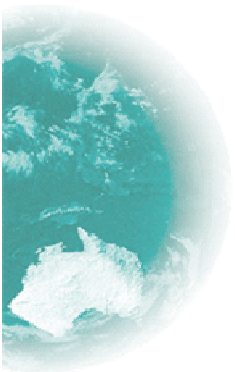
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# Reviewers

TGA uses -

internal evaluators ( quality and chemistry control, laboratory, pre-clinical and clinical), and

external evaluators (quality and chemistry control, pre-clinical and clinical) and has an Expert Evaluation panel established by tender





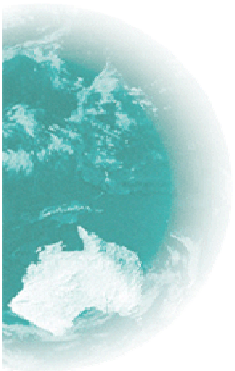
# Advisory Committees

TGA seeks advice from independent expert committees

For new prescription medicines TGA uses the Australian Drug Evaluation Committee

It has two subcommittees:-

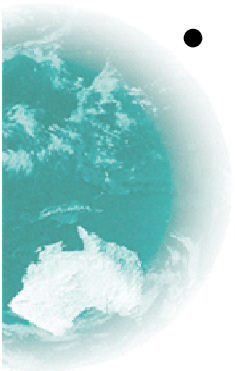
- Pharmaceutical Subcommittee (c & qc)
- Adverse Drug Reactions Advisory Committee (post market monitoring)





# Evaluation phases

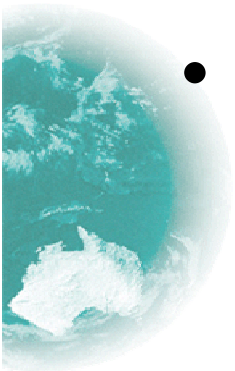
- Application entry phase for data filtering
- Evaluation phase, with information exchange between sponsor and TGA
- Peer review/acceptance of reports
- +/- advisory committee phase ( for nce and some eoi) or peer review
- decision making phase, including finalisation of labelling
- All products must have a TGA approved product information for health professionals and a Consumer Medicine Information document for patients.





# Decision making

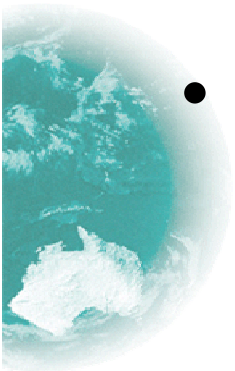
- Decisions are made by delegates of the Secretary, who are in-house TGA officers
- All decisions are able to be appealed
- Appeals can go to a Minister's delegate, a merit review body (AAT), or the Federal court if on a matter of law.





## Matters that must be considered under the legislation

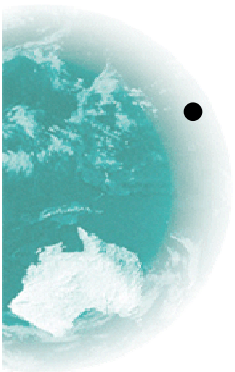
- Establishment of quality, safety and efficacy for intended purpose
- Presentation
- Conformance with standards
- Manufacturing- GMP





# Sponsor involvement

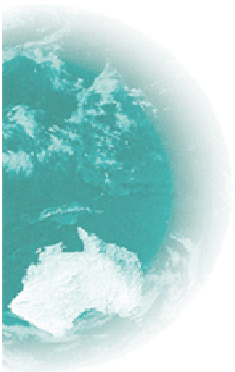
- In addition to informal and formal exchange of information during the evaluation phase,
- Sponsors are provided with copies of all completed evaluation reports. Comment is specifically sought on any errors, omissions or issues of concern
- Sponsors are also provided with a copy of the draft decision and invited to comment direct to the advisory committee





## In addition data

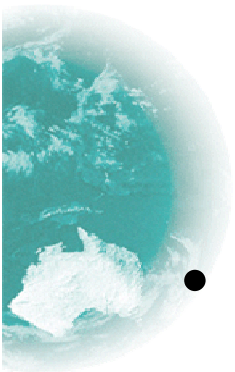
- May be lodged during the evaluation phase with prior agreement of TGA
- May be lodged in response to TGA raising an issue in a report





# Use of unapproved medicines

- TGA also administers arrangements to access unapproved therapies
- - Special Access Scheme
  - For individuals
  - For specialist prescribers
- - Clinical trial programs

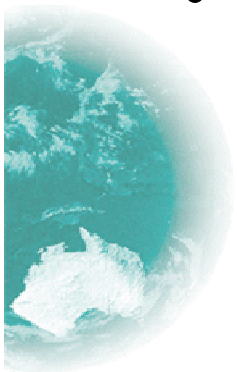




# Clinical trials

- Two clinical trial systems operate, CTN and CTX
- CTN - notification scheme based on approval of responsible Institutional Ethics Committee
- CTX- approval scheme based on safety assessment by TGA

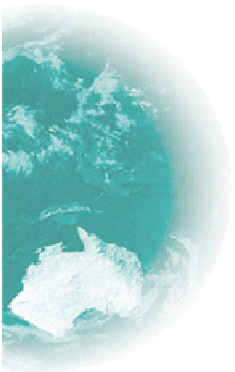
**MAJORITY OF TRIALS PERFORMED UNDER CTN SYSTEM**





## Clinical trials (2)

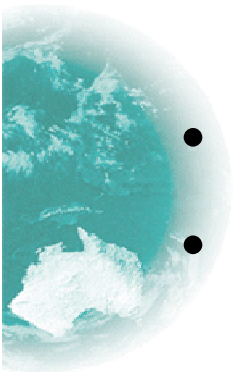
- ALL TRIALS
  - must be conducted in accordance with the ethical standards set out in the National Statement on Ethical Conduct in Research Involving Humans (published by Aust NHMRC) and Guidelines for Good Clinical Practice (published by ICH and CHMP)





## Post market- shared roles

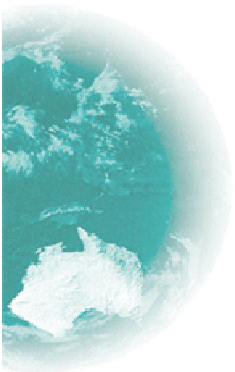
- Requirement for submission of PSUR
- Laboratory testing, as required
- Problem report and recall management
- ADR reporting- compulsory for sponsors and encouraged by others
- Ongoing review of GMP of manufacturing
- Safety review and update of PI as required





# Future Directions

- Regulatory reform
  - Access to Medicines Working Group (AMWG) initiatives with industry, HTA and regulator
  - Streamlining of TGA review processes
  - Increased transparency initiatives
  - eCTD





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<http://www.tga.gov.au>

