



Australian Government

Department of Health

Therapeutic Goods Administration

Use of Regulatory Reliance for Advanced Therapy Medicinal Products

An Australian perspective

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TGA Health Safety
Regulation



Overview

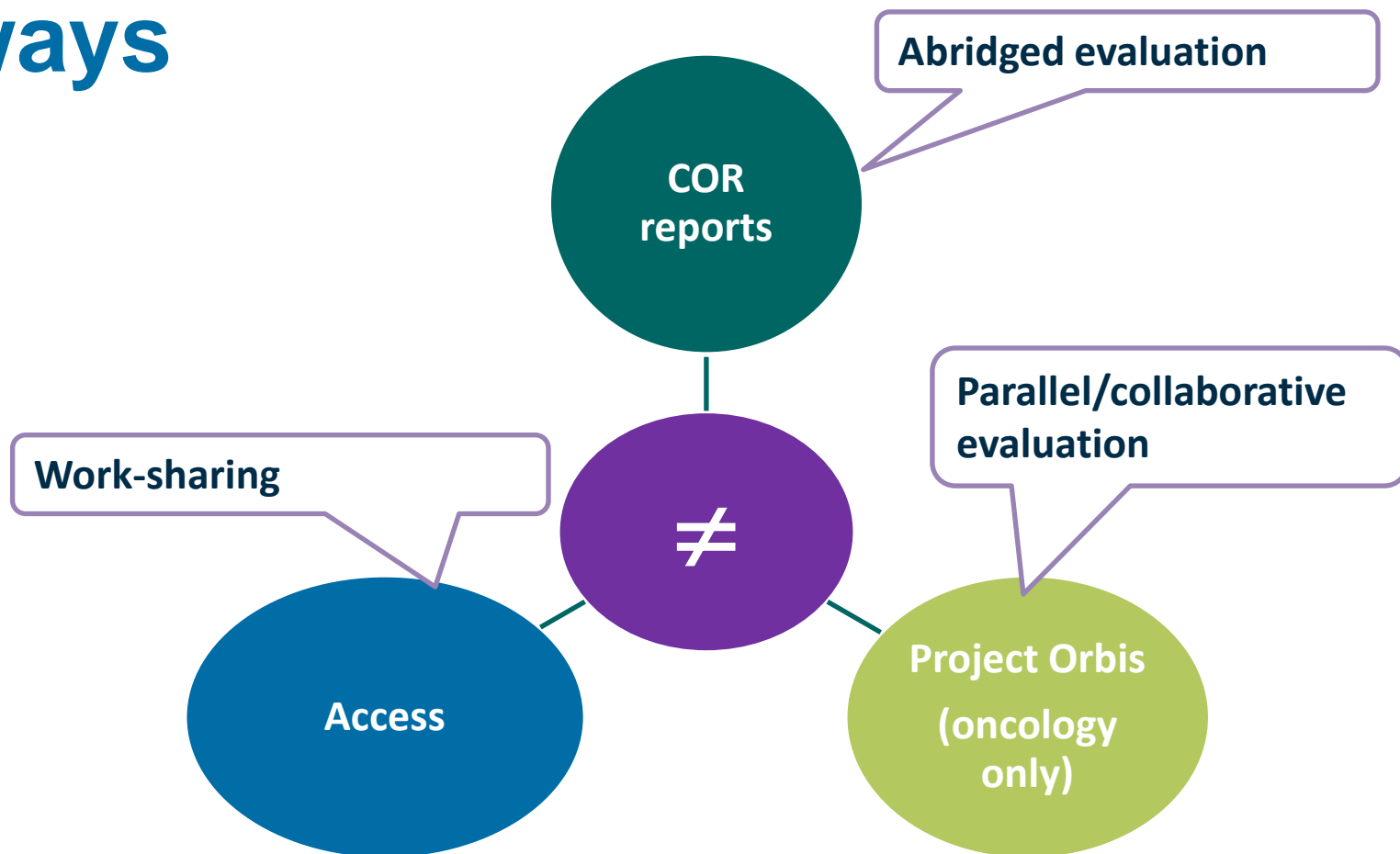
- Overview of TGA's reliance pathways and principles
- Use of comparable overseas regulator (COR) reports to abridge assessments
- Work-sharing via the Australia-Canada-Singapore-Switzerland-United Kingdom Consortium (Access)
- Access work-sharing and ATMP?



TGA reliance pathways

Key principles:

- TGA sovereignty over decision making
- Reliance **does not** represent a less robust form of regulation
- Regulators we work with have similar values and approaches to critical decision-making
- Reliance provides flexibility to TGA/applicants and can be tailored to the needs of the regulatory system



Industry's support and adherence to these principles is vital to the success of these pathways

COR report-based process

- The TGA uses assessments from Comparable Overseas Regulators (CORs)
- Key features:
 - a list of countries and jurisdictions from whom TGA will accept reports (CORs)
 - transparent criteria and guidance for identifying CORs
 - a process for using overseas reports
- The TGA will only evaluate data generated specifically for the Australian context



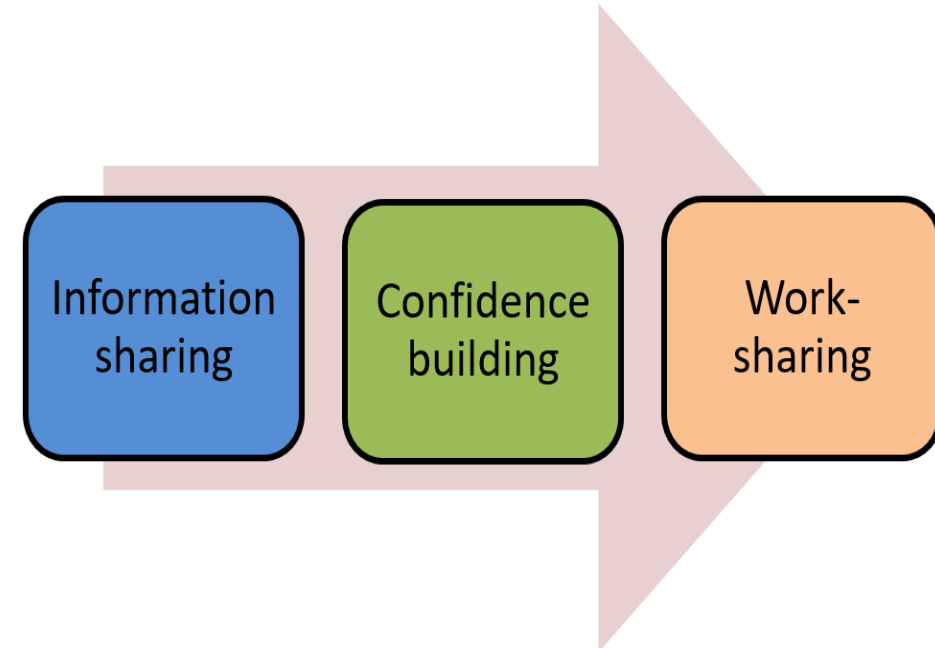


Access New Active Substance (NAS) Work Sharing Initiative

- The Australia-Canada-Singapore-Switzerland-UK (Access) Consortium is a group of like-minded, medium sized regulatory authorities.
- Since 2007, Access partners have been sharing information and exploring opportunities for work-sharing in areas including:
 - generic medicines registration
 - new prescription medicines
 - post-market medicine safety
 - development of technical guidelines.



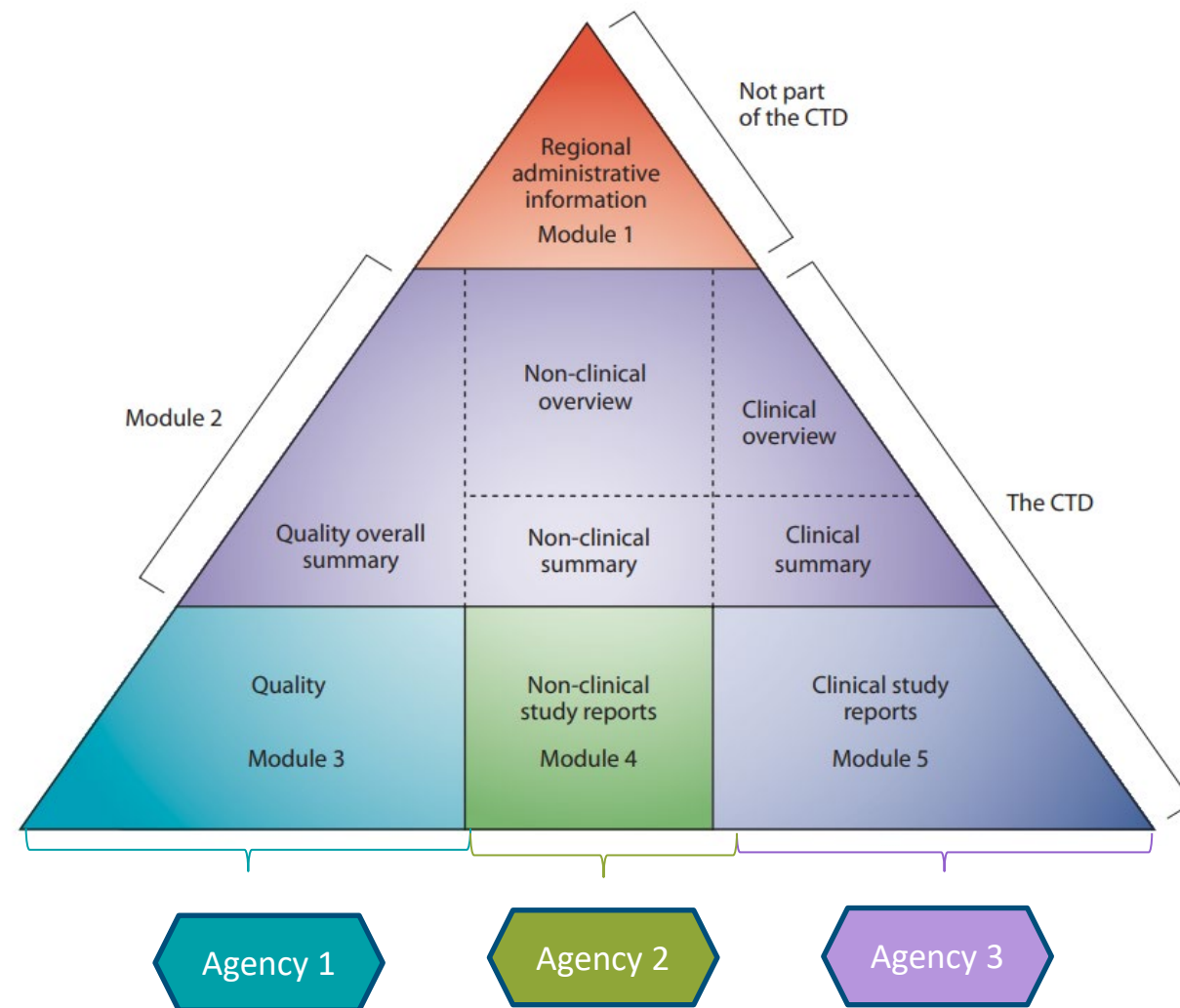
Journey to international work-sharing.....



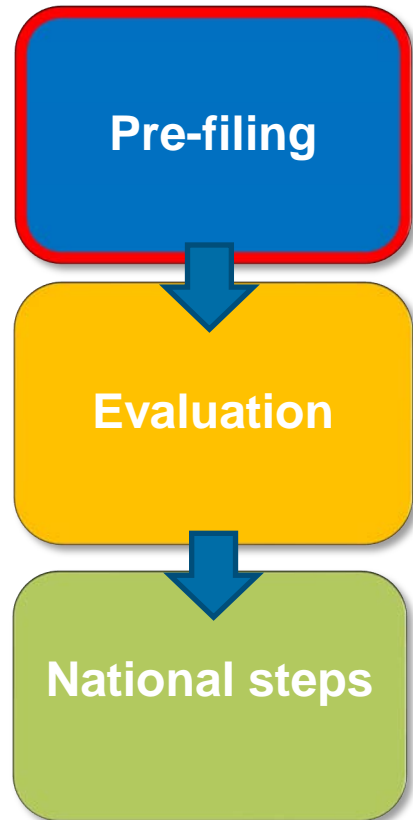


What is Access work-sharing?

- Global collaborative review program for drug applications
 - new drugs (new active substances)
 - new indications
- Key features:
 - Divided/shared review of the dossier
 - Information sharing via bilateral confidentiality agreements and Memoranda of Understanding
 - Sovereign decision-making



Access work-sharing process



- Applicant Expression of Interest (EOI) *at least 3 months* before the intended filing date.
- Agreement of partner regulators to participate
- Participating regulators negotiate a division of labour and joint-review timeline, e.g.:
 - Mod 3 – Quality
 - Mod 4 – Non-clinical
 - Mod 5 – Clinical
- Evaluation plan tailored to each submission through negotiation

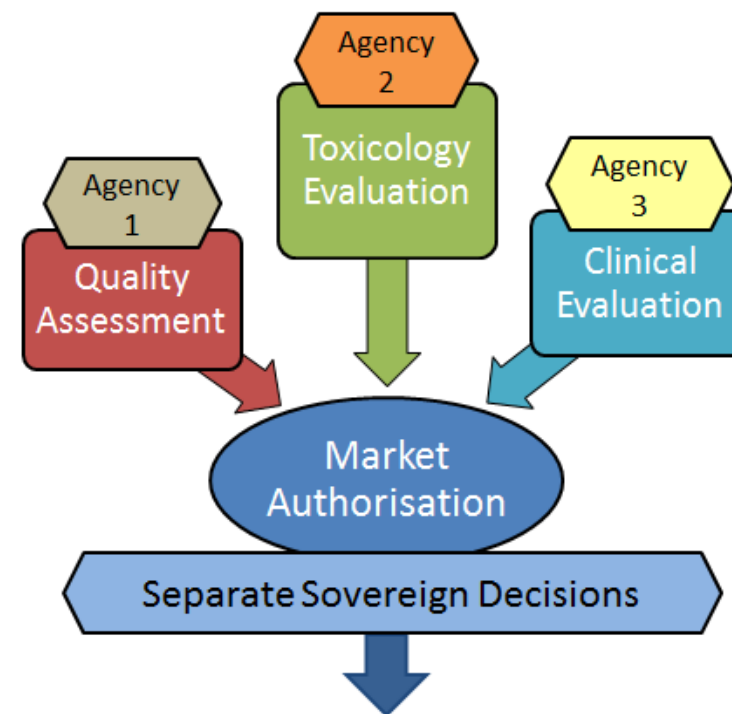




Access work-sharing process



- Agencies evaluate their assigned module(s) and any country specific aspects:
 - Mod 1 (labels, GMP, RMP)
 - Mod 3 (TGOs, stability, container)
 - Mod 4 (pregnancy category)
 - Wording of indications
- Consolidated technical questions
- Inter-agency interactions throughout the review (evaluator t/c)





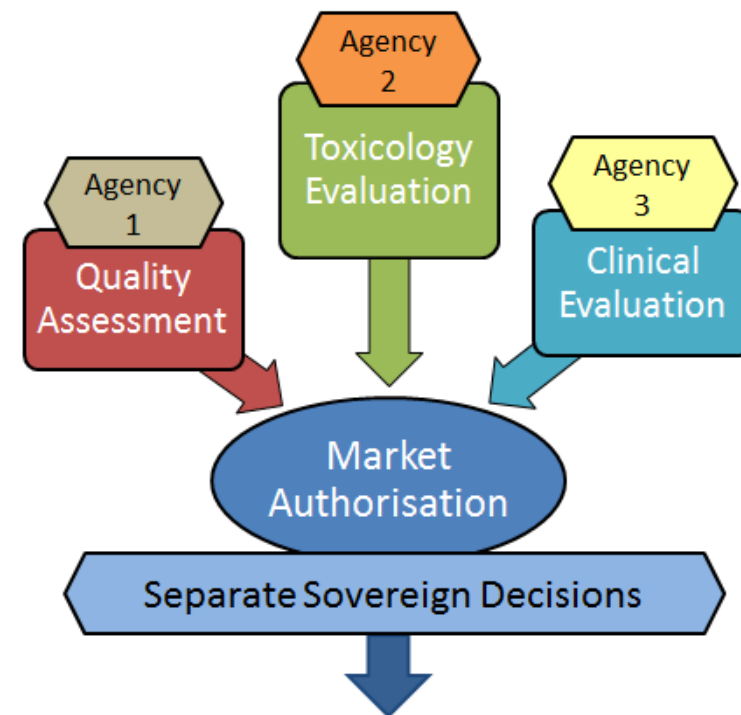
Access work-sharing process

Pre-filing

Evaluation




























National steps

- Work-sharing concludes at the end of the evaluation
- **National steps include:**
 - expert advice
 - wording of indications
 - Finalisation of product label
 - subsidy/reimbursement
- Independent decision-making by each jurisdiction
- **Near** simultaneous decisions BUT reimbursement is not part of work-sharing.





Access – Completed submissions

Submission	Indication	Quality	Non-clinical	Clinical	Approval
ERLEADA (apalutamide)	Prostate cancer			 	July 2018
VERZENIO (abemaciclib)	Breast cancer				April 2019
ZEJULA (niraparib)	Ovarian cancer				June 2019
XOFLUZA (baloxavir marboxil)	Anti-viral (influenza)				Feb 2020
NUBEQA (darolutamide)	Prostate cancer				Feb 2020
VYNDAQEL/VYNDAMAX (tafamidis/tafamadis melumine)	Cardiomyopathy			 	March 2020
SARCLISA (isatuximab)	Multiple myeloma				April 2020
KISIMPTA (ofatumumab)	Multiple sclerosis			 	March 2021

****11 submissions currently under evaluation**

6 EoI currently under consideration by Access agencies



TGA's experience with Access work-sharing

Benefits

- Encourages earlier submissions to Australia
- Reduced duplication
- Sharing resources and expertise
- Collaborative approach to decision making leading to more robust decisions
- Exposure to emerging trends, innovations and learnings
- Potential access to multiple markets near simultaneously

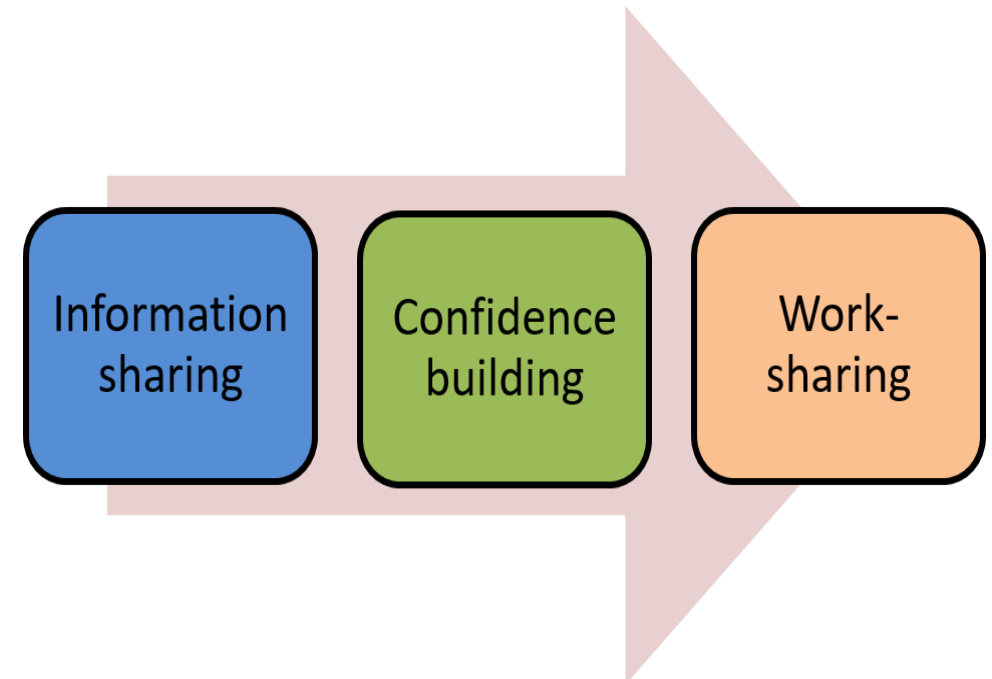
Challenges

- Resource implications for both the coordination and evaluation aspects
- Different processes – decision makers, transparency
- Different national requirements, TGOs & different sovereign decisions
- Operating as a “pilot” to date – each application has been unique



Work-sharing ATMP - challenges

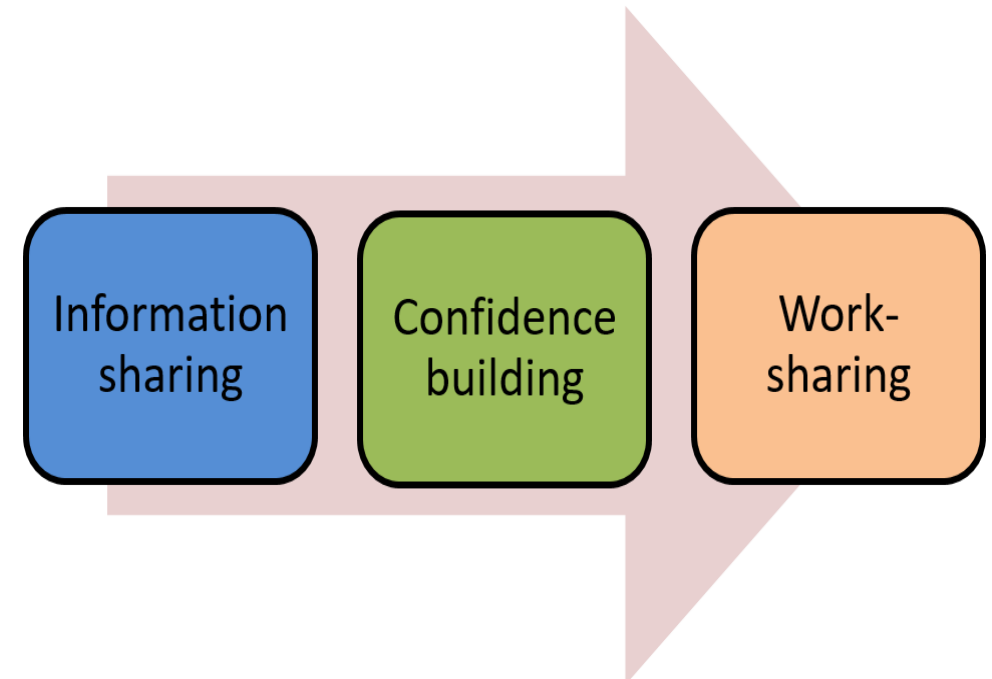
- Lack of common experience between Access agencies due to novelty of products
- Uncertainty around regulatory approaches, e.g.:
 - Benefit/risk assessment
 - Use of novel or surrogate endpoints
 - environmental risk assessments
 - availability of accelerated pathways
- Need to be sure each agency can meet regulatory timeframes/standards





Work-sharing ATMP - getting the ball rolling...

- Differences in approaches between agencies does not necessarily preclude collaboration
- Early interactions with regulators vital to assess whether work-sharing is feasible
- Applicants need to be agile and willing to contribute to regulatory innovation
 - “building on the run”
 - different collaboration options available
 - Information sharing
 - Parallel review
 - Work-sharing





Further information

Comparable Overseas Regulator Pathway

- [Comparable overseas regulators \(CORs\) for prescription medicines](#)

Access work-sharing

- [ACSS - NAS work sharing initiative](#)
- [Guidelines for Industry](#)
- [Frequently asked Q&A](#)

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