



Australian Government

Department of Health

Therapeutic Goods Administration

Improving the exchange of information between national regulatory authorities - Challenges and opportunities

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TGA Health Safety
Regulation



Challenges - information exchange btn regulators

- a secure process is used (eg Eudralink, secure sharepoint site)
- Language (Are all communications in English?)
- Familiarization of international regulatory framework
 - National guidelines
 - Areas of regulatory divergence (provisional applications, Pharmacovigilance frameworks)
 - Differences R/B analysis





Using exchanged information to make sovereign regulatory decisions for PMs

- Divergence in Regulatory frameworks
 - Use of different therapeutic guidelines, criteria and policies
 - Understanding the different:
 - types of evaluation reports & communications
 - decision making processes (rapporteur/co-rapporteur/delegate/ Expert committee)
 - Post-market frameworks → R/B analysis
 - Availability of unredacted *de novo* evaluation reports and all associated communications



Opportunities for increasing the scope of regulatory activities

- Initial marketing authorizations & variations
- Compliance with Good Manufacturing Practices
- Pharmacovigilance activities
- Exposure to emerging global trends & innovation
- Information-sharing = first-step in building confidence → work-sharing



Information sharing

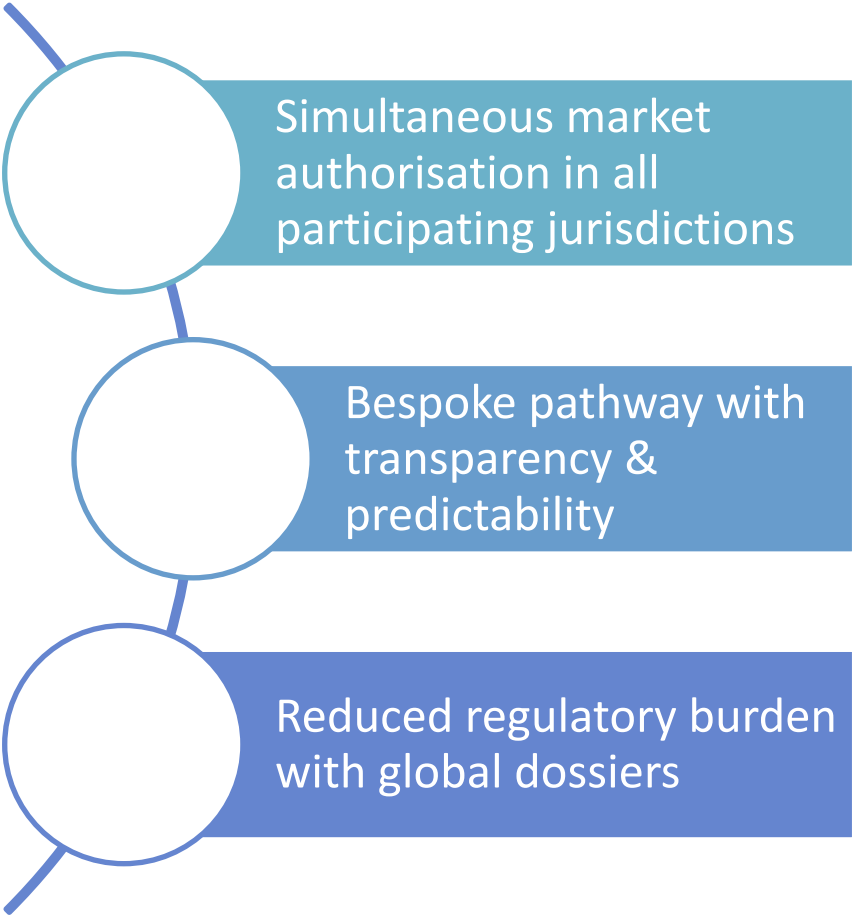
Confidence building

Work-sharing



Work-sharing – Benefits for all

Industry

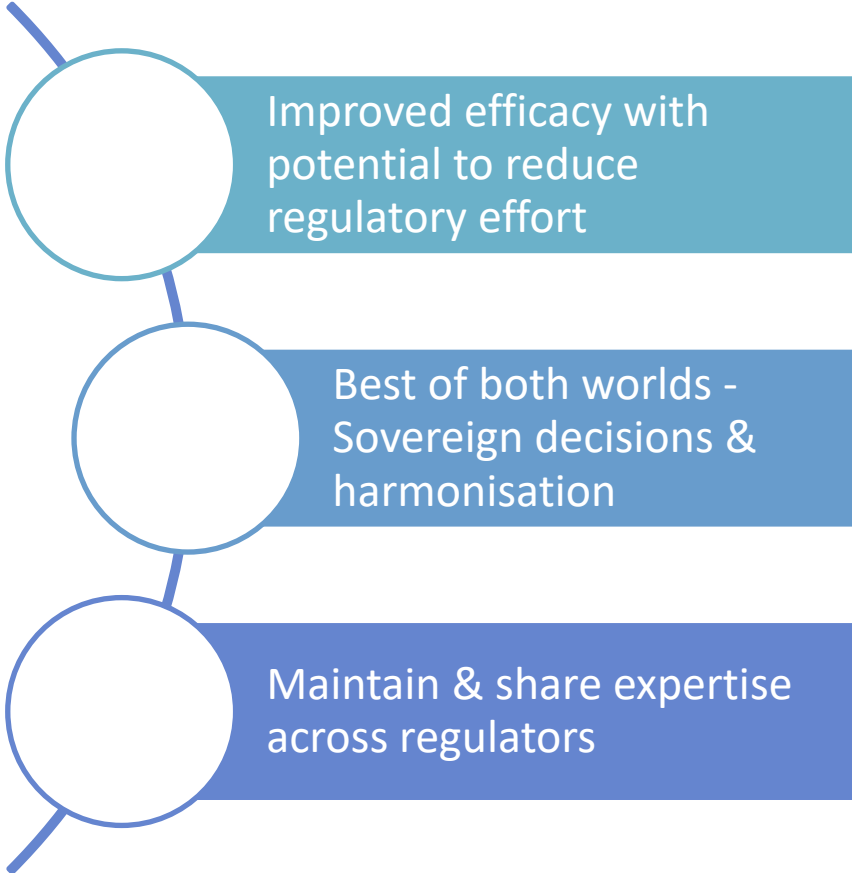


Simultaneous market authorisation in all participating jurisdictions

Bespoke pathway with transparency & predictability

Reduced regulatory burden with global dossiers

Regulators



Improved efficacy with potential to reduce regulatory effort

Best of both worlds - Sovereign decisions & harmonisation

Maintain & share expertise across regulators