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 polices
  - 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

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