Australian Government
Department of Health
Therapeutic Goods Administration

Risk management plans – an overview

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ARCS-TGA workshop

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TGA Health Safety Regulation

Australian Government
Department of Health
Therapeutic Goods Administration

Outline

- What are RMPs and why are they needed?
- How does the TGA evaluate RMPs?
- Guidance on developing RMPs

Why have RMPs been required?

- Limited information from clinical trials (CTs)
- Not always representative of real world usage due to inclusion and exclusion criteria in CTs
- Potential risks identified but not fully characterised during CTs
- Missing information in certain population groups – children, pregnant women and the elderly

What is a risk management plan for?

Outlines the risk management system for a medicine once it is available for use in Australia.

Comprises:

- Known safety profile
- Identified and potential safety concerns and where appropriate how they will be mitigated
- Missing safety information where this is known or can be predicted and how this will be managed

Focuses on:

- Monitoring – Pharmacovigilance Plan
- Minimising risks associated with the use of the product – Risk Minimisation Activities

Provides:

- Coverage of the life cycle of the product
- Assurance that all risks related to the use of a medicine have been considered and acted upon

Risk minimisation activities

- Routine risk minimisation activities include
  - Product Information
  - Consumer Medicines Information
  - Directions for use document
  - The labelling
  - The pack size and design
  - The legal (prescription) status of the product
- Additional risk minimisation activities include
  - Education programs for patients
  - Health care professional education programs
  - Dear Health Care Professional letters
  - Controlled access programme

→ For each safety concern a risk minimisation activity is assigned in the RMP

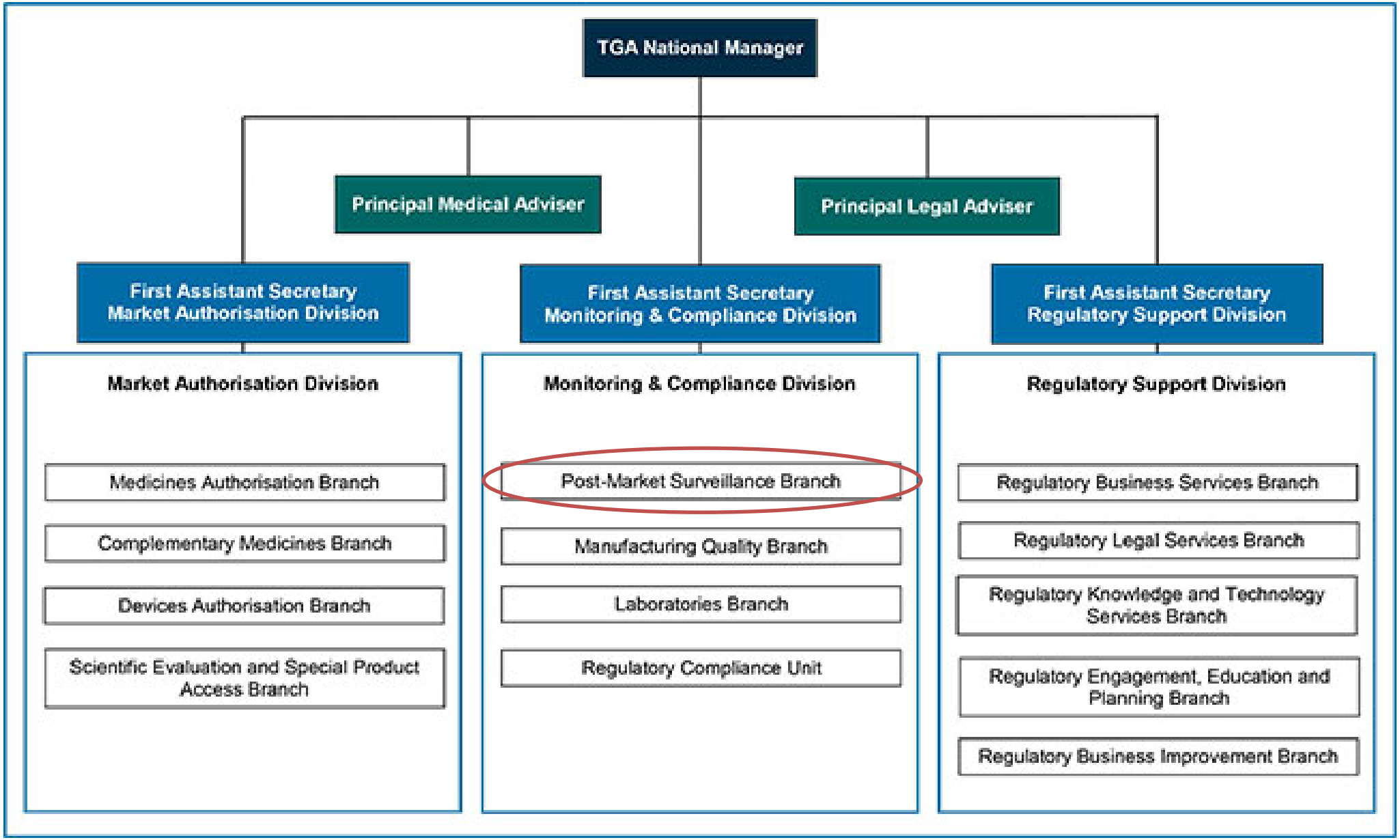
Pharmacovigilance Plan

- Routine pharmacovigilance includes
  - Collection, follow-up and reporting of adverse events
  - Analysis of data and reporting in Periodic Safety Update Reports (PSURs)

- Additional pharmacovigilance includes
  - Clinical trials
  - Post-authorisation safety studies
  - Drug utilisation studies
  - Patient registries
  - Physician surveys
  - Prescription event monitoring

→ For each safety concern a pharmacovigilance activity is assigned in the RMP

The RMP evaluation team


TGA National Manager
Principal Medical Adviser
Principal Legal Adviser
First Assistant Secretary
Market Authorisation Division
First Assistant Secretary
Monitoring & Compliance Division
First Assistant Secretary
Regulatory Support Division
Market Authorisation Division
Medicines Authorisation Branch
Complementary Medicines Branch
Devices Authorisation Branch
Scientific Evaluation and Special Product Access Branch
Monitoring & Compliance Division
Post-Market Surveillance Branch
Manufacturing Quality Branch
Laboratories Branch
Regulatory Compliance Unit
Regulatory Support Division
Regulatory Business Services Branch
Regulatory Legal Services Branch
Regulatory Knowledge and Technology Services Branch
Regulatory Engagement, Education and Planning Branch
Regulatory Business Improvement Branch

Post-market surveillance branch

Dr Jane Cook

Signal investigation (medicines)

Risk management plan evaluations

Device vigilance and monitoring

Recalls and advertising

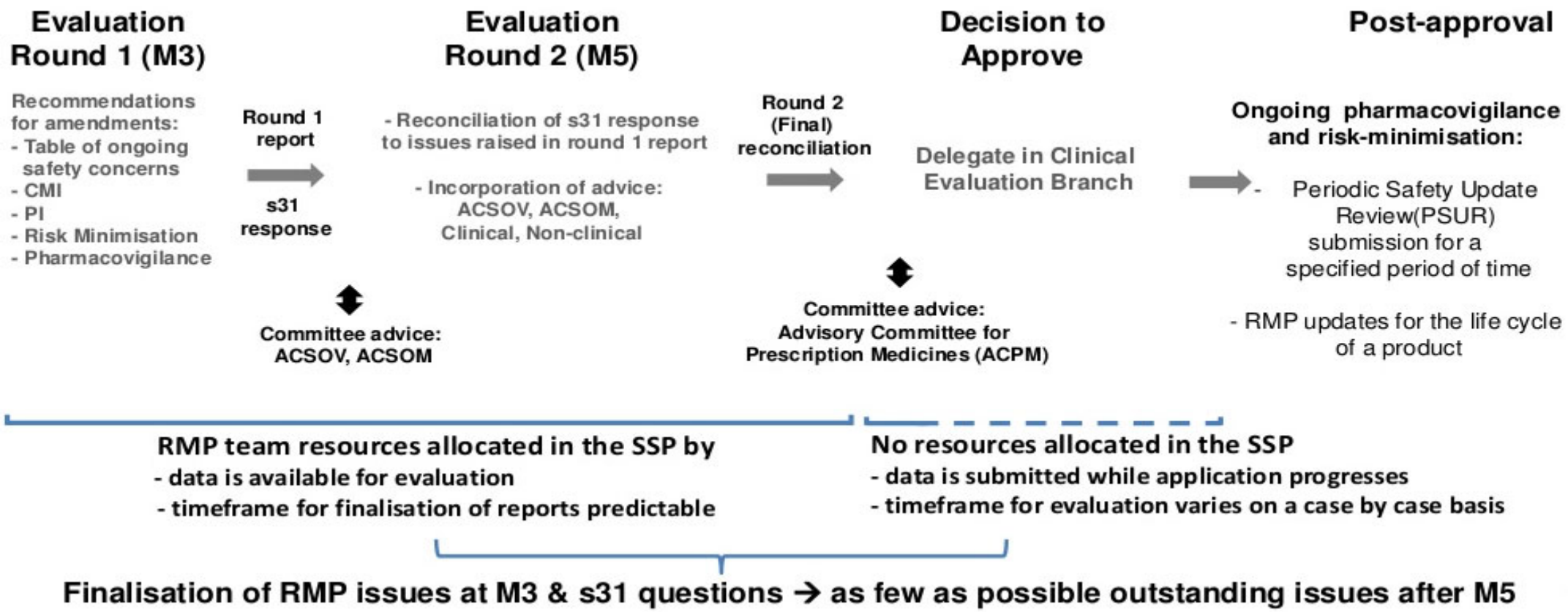
Advisory committees

Technical projects and communications

RMPs to date

Year	Number of RMPs evaluated
2009	8
2010	70
2011	50
2012	82
2013	131

Workflow of a RMP evaluation



Updated Q&As and ASA

- Proposed updated Q&As and ASA template sent to Medicines Australia and GMIA for members' comment (Nov 2014)

- Main themes of feedback
  - Reduce duplication
  - Clarify process

- We have amended Q&As and ASA template in response to your feedback

Guidance

- RMP Questions and Answers
- Australian-specific Annex Template
- Mandatory requirements for an effective application
- EMA Guideline on good pharmacovigilance practices: Module V – Risk management systems
- RMP co-ordinator (rmp.coordinator@tga.gov.au)

RMP requirements in Australia

- TGA follows EMA RMP guidelines
- RMP submitted should be the most recent EU-RMP
- Core RMP with ASA or Australian RMP acceptable if no EU-RMP exists

Tips for a smooth process

- Make sure all the information asked for in the ASA template is provided
- There is no “one size fits all” approach – judgement required
- Provide all documents referred to in the RMP and ASA
- Whenever there’s an update, state clearly what has changed and why
- Provide all required information at submission or at s31 response
- Address all RMP evaluator recommendations
- No submission of data during evaluation unless requested by TGA or by prior agreement

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