



Australian Government
Department of Health
Therapeutic Goods Administration

Risk minimisation in the Australian context

Dr Claire Larter
Acting Co-Director, Risk Management Plan Evaluation Section,
Pharmacovigilance & Special Access Branch
Medicines Regulation Division, TGA
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TGA Health Safety
Regulation

Presentation overview

- What is risk minimisation?
- General principles for risk minimisation plans
- Tools available for risk minimisation
- How to describe your risk minimisation plan in the ASA

What is risk minimisation?

- Part of risk management → described in the RMP
- Intended to improve ***patient outcomes***
 - Optimise risk: benefit
 - Minimise harm
- Includes both risk ***prevention*** and risk ***mitigation***
 - Some risks are neither preventable or able to be mitigated
 - May be acceptable depending on benefit



Risk minimisation requires understanding the risks of the product

- Inherent risks, including:
 - Likelihood
 - Severity (including reversibility)
 - Preventability
- Risk factors in the population
- Intended and potential use



General risk minimisation principles

- Iterative process that continues throughout the lifecycle of the product
 - Pre-registration → plan to minimise risks identified during development, know where the gaps are
 - Post-registration → address emerging risk
- Consider the burden of risk minimisation
 - On patients and the healthcare system
 - Burden should be proportionate to risk



Developing an effective risk minimisation plan

- Appropriate tool selection
 - Choose most effective tool to achieve an objective
- Must be well planned
 - Clear goals
 - More likely to succeed if integrated into the health system
 - What success is should be well defined and measurable
 - Process indicators
 - Outcome indicators
 - Plan should be adapted as necessary



Risks requiring additional risk minimisation should be carefully selected

- Are there risks that cannot be minimised by routine measures?
- This requires knowledge of the medicine:
 - Indication, population, risks
 - Overall risk-benefit
 - Setting of use
 - Will “real-world” use likely differ from intended use?
 - Potential for misuse

Need to consider how these factors may interact

Risk minimisation tools

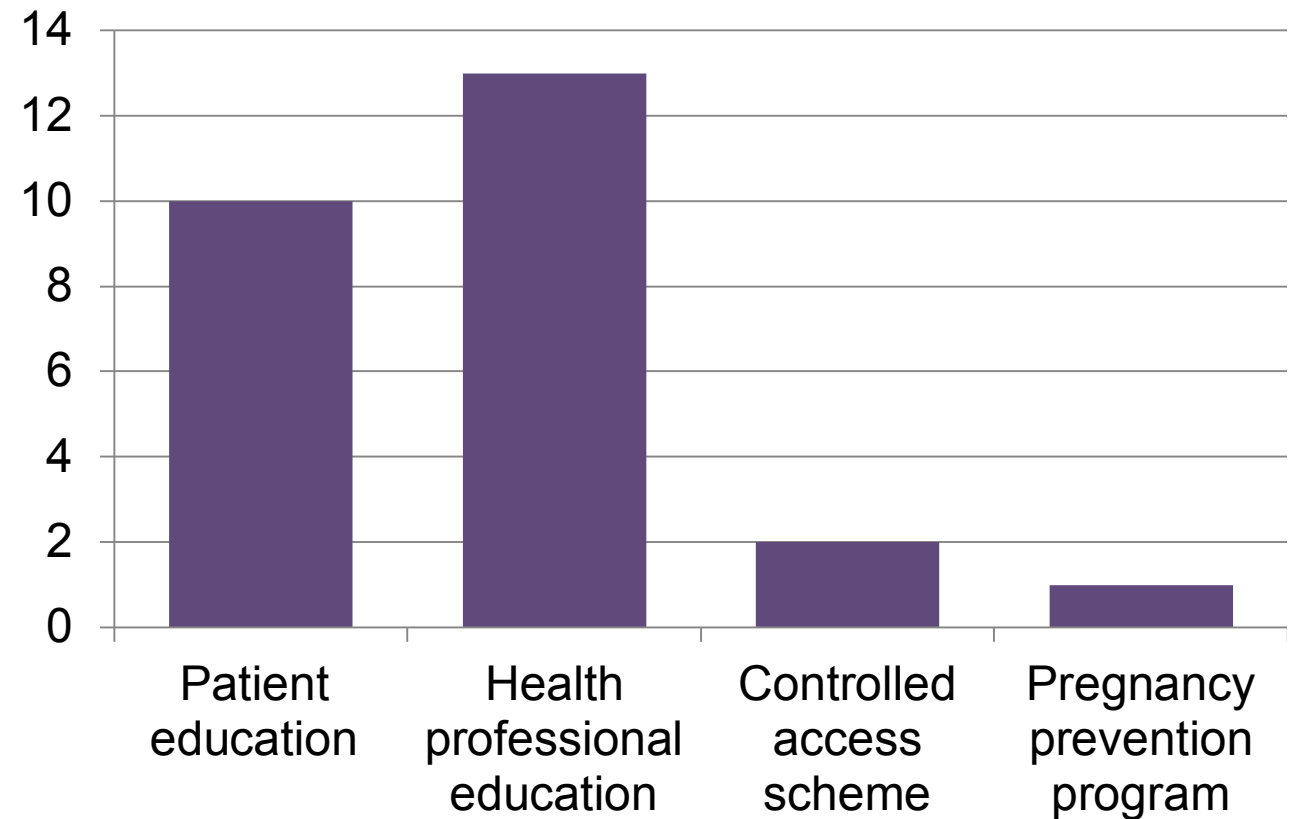
| Routine | Additional |
|-------------------------------|-------------------------------------|
| Product Information | Patient education |
| Consumer Medicine Information | Patient Alert Cards |
| Product labeling | Healthcare profession education |
| Legal (prescription) status | Dear healthcare professional letter |
| Pack size & design | Safety device design |
| | Restricted access |
| | Patient registry |

Selecting the appropriate tools

- Will depend on the following factors:
 - **Risk identification:** recognition (existence of a risk) and characterisation (level of risk)
 - **Goal setting:** goals, objectives and targets
 - **Health care system integration:** adaptation to local requirements
 - **Evidence-based activities:** based on scientific literature or other evidence
 - **Proportionality/Burden considerations:** reasonable minimisation-burden balance
- A comprehensive strategy may require a range of interventions

Commonly used tools in Australia

- 37 RMPs were evaluated for new chemical entities in 2015.
- 26 included additional risk minimisation activities
- Education was the most common activity



Patient Education

- Patient brochures, websites for patients
- Targeted to specific patient populations
- Useful for products where patient behaviors can influence safety



| Advantages | Disadvantages |
|--|---|
| Promote appropriate use | Requires periodic assessment ± updating |
| May increase early detection of AEs | Can be a burden for dispensers |
| Reinforce instructions given by healthcare professionals | May be dependent on health literacy |
| | May be perceived as marketing |

Healthcare professional communication

Dear healthcare professional letters

- Useful for:
 - Medicines that require adherence to special guidance to manage risks
 - Changes in indication that may involve a different dosing regimen
 - Emerging safety concerns

Advantages = Broad and rapid dissemination of information

Disadvantages = Effect can fade over time
Can be overlooked

Healthcare professional communication

- **Prescribing/ dispensing guides**

- Useful for complicated dosing regimens, managing drug-drug interactions or medicines that may require dose adjustments, etc...

- **Targeted education**

- Useful for medicines that require additional monitoring (e.g. renal function), different use in different populations, etc...

Advantages

Enhance prescriber knowledge

Clinically useful – can keep for future reference

Can be integrated into continuing professional development activities

Disadvantages

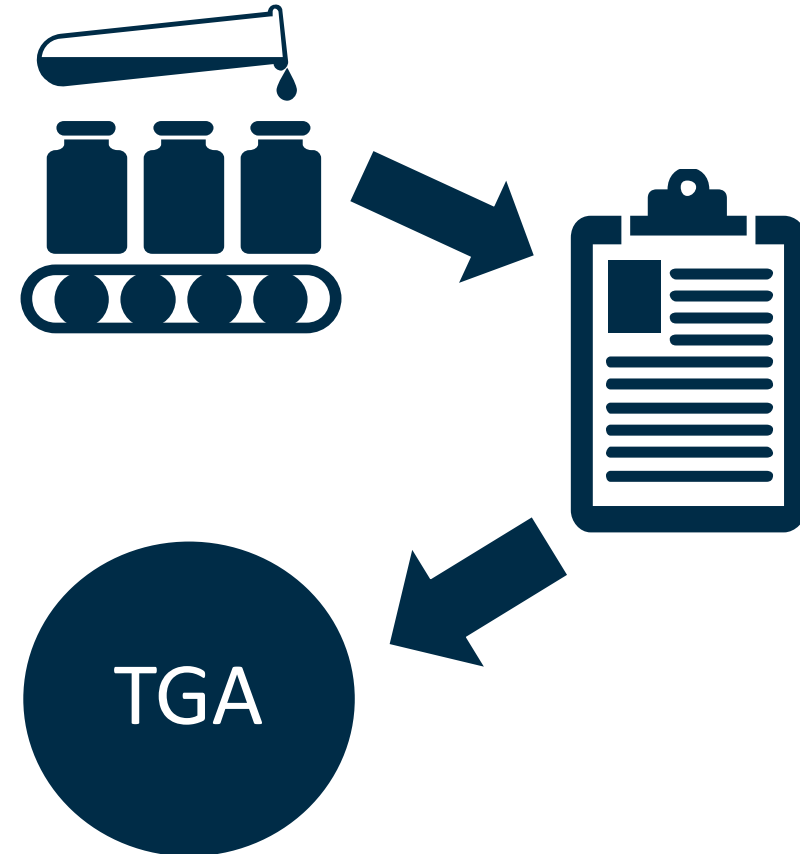
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Restricted access schemes

- Less commonly used
- Different models
 - Patient registration
 - Prescriber/ dispenser certification
 - Dispensing linked to test confirmation
 - Certain types of prescribers
- Detailed documentation critical
 - How the system will work
 - How it will be checked for effectiveness



Describing risk minimisation in the ASA

- Follow the template

Australian-Specific Annex template

3. Risk minimisation plan

3.1. How risk minimisation activities will be implemented in Australia.

3.2 Potential for medication errors or other risks if applicable

3.3 How risk minimisation activities will be evaluated in Australia

4. Summary of the RMP

Consider what is different about Australia?



What are the features of our health system, medical practice, geography, population and culture that could influence how risk minimisation tools are selected and implemented?

- Indigenous population
- Large Asian population
- Rurality/ lack of access to specialist services
- State vs federal control over some aspects of how medicines are used
- Access to health professionals and information

Key areas in the ASA for risk minimisation

- Compare activities between EU and Australia for all safety concerns
 - Identify and justify differences
 - Describe local implementation
 - Include exact wording of PI statements
- Include evaluation plan
- Include any proposed educational materials as an appendix





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