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THIRD PLENARY:
Risk Sharing Agreements: Country Experiences, Challenges, and Lessons Learned

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Risk Share Arrangements in Australia

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- Medicines Australia represents the discovery-driven pharmaceutical industry in Australia.
- We are a key policy stakeholder for Government.
- We want to achieve a predictable and positive environment for the registration and reimbursement of medicines.
- We engage with key stakeholders including consumer groups, Government, groups representing healthcare professionals as well as others.
- In line with the Government's National Medicines Policy, we strive to strengthen our industry, to ensure patients continue to access the medicines they need and to ensure our industry contributes to economic growth.

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Member Companies

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Health Technology Assessment in Australia

- In order to list a new medicine on the national reimbursement list, the **Pharmaceutical Benefits Scheme** (PBS), the Minister of Health requires a positive recommendation by the **Pharmaceutical Benefits Advisory Committee** (PBAC).
- Current annual net expenditure for the PBS is around $9 billion.
- The PBAC considers a range of factors in its decision-making process including clinical effectiveness, cost-effectiveness and overall cost.
- The PBAC also considers the uncertainty around these factors.
- Occasionally, the PBAC may consider that a risk share arrangement is required to deal with a specific uncertainty.

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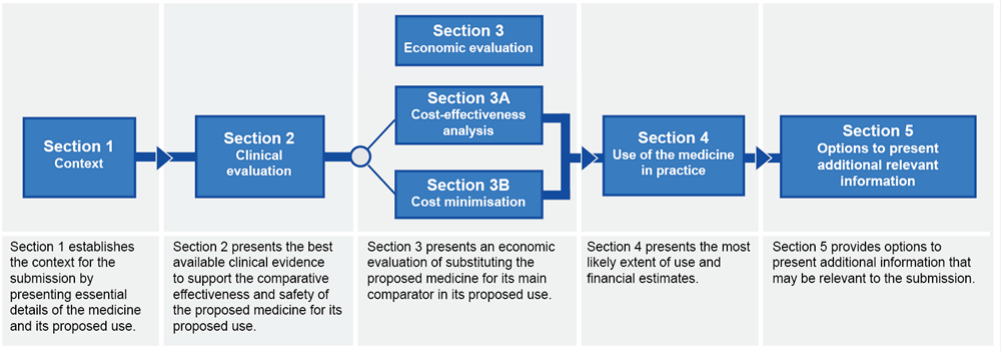
Contents of a submission to PBAC

Submission structure for a major submission



Source:
http://www.pbs.gov.au/info/industry/listing/listing-steps

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The PBAC Guidelines around risk share arrangements

- Risk share arrangements are not mandatory – it is up to the sponsor to propose a risk share arrangement in the submission or to accept one if deemed necessary by the PBAC.
- The sponsor can propose a risk share arrangement to deal with a specific issue or risk that the PBAC is trying to manage, usually:
- The number of eligible patients
- The potential for use in a non-subsidized population
- The potential for use beyond disease progression
- The risk share arrangement is captured through a legal deed of agreement ('deed') that is negotiated between the sponsor and the Government
- Some financial risk share arrangements can be class deeds where sponsors share the risk based on market share.

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The 'Deed'

- The risk share arrangement deed is a legal contract that binds the sponsor and the Government.
- The Government is reluctant to make changes to any of its standard clauses as this places burden in terms of monitoring and managing the deed.
- It also places a lot of burden on the sponsor especially when entering a 'class deed' where the clauses have already been negotiated.
- The deed will usually cover matters such as:
  - The medicine(s) and specific PBS indication being managed
  - Risk share caps or other specific terms e.g. provision of data
  - Payback formulas and terms
  - When to expect invoices from the Government
  - How confidential information is managed
  - Termination and/or continuation as well as how to deal with disputes

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Types of Risk Share Arrangements

- Risk share arrangements tend to be:
  - **Financial** (e.g. price-volume, rebate or discount based schemes) or
  - **Performance-based** (e.g. continuation rules, outcomes guarantees, coverage with evidence development).
- The PBAC guidelines define performance-based risk shares as:
  "involve a plan by which the performance of the medicinal product is tracked in a defined patients population over a specified period of time and the level or continuation of reimbursement is based on the health and economic outcomes achieved"

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Managed Entry Schemes

- Medicines Australia signed a memorandum of understanding with the Government in 2010 to support the introduction of certain new medicines under a managed entry process.
- In January 2011, the PBAC commenced assessment of certain medicines for which the price was based on current evidence with a potential to adjust the price pending additional clinical and cost-effectiveness evidence to support a higher price.
- The framework enacted via a deed to support managed entry schemes included:
  - Recognition of a high clinical need for the medicine.
  - Provision of new clinical data within a pre-specified timeframe.
  - Additional consideration of new clinical data and economic evidence.

For further information: http://www.pbs.gov.au/info/publication/factsheets/shared/framework-for-introduction-of-managed-entry-scheme-for-PBAC-submissions

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Data on Risk Share Arrangements

- The Government does not publish data on the number of the different types of risk share arrangement in existence.
- 11 managed entry scheme medicines (2010-17) were identified by Tuffaha and Scuffham.
- A financial risk share was mentioned for 24 medicines in the most recent public summary documents (PBAC meeting March 2018).
- Limited information has been published:
    - Tuffaha and Scuffham. Pharmacoeconomics, 2018, 36: 555-565
    - Kim et al. Journal of Pharmaceutical Policy and Practice. 2018, 11:4
    - Robinson et al. International Journal of Technology Assessment in Health Care, 2018, 34: 46-55.
    - Lu et al. Journal of Pharmaceutical Policy and Practice, 2015, 8:6
    - Vitry & Roughead. Health Policy 117, 2014: 345-352.

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Limited regional data

Table 1 Patient access schemes in the Asia-Pacific region by country, type and condition

	Australia	South Korea	New Zealand	Total
Types				
Outcome-based	21	-	-	21
Evidence generation	3	-	-	3
Financially-based	33	3	5	41
Hybrid*	41	-	-	41
Conditions				
Cancer	29	-	2	31
Inflammatory Conditions	28	-	1	29
Infectious Disease	7	-	-	7
Pulmonary Hypertension	7	1	1	9
Other	27	2	1	30
Technology				
Pharmaceuticals	95	3	5	103
Medical devices	3	-	-	3
Subtotal	98	3	5	106

*Hybrid schemes involved both pricing arrangements and conditional treatment continuation

Lu et al, 2015

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Case Study – managed entry scheme

- **Crizotinib** is indicated for second-line treatment for ALK positive advanced non-small cell lung cancer (NSCLC).
- Initially considered by the PBAC in 2013 but rejected.
- Recommended by the PBAC for PBS listing at its November 2014 under a managed entry scheme to deal with uncertainty regarding the magnitude of clinical benefit. The price would be maintained or reduced based on additional clinical and cost-effectiveness evidence.
- 1-year survival data was requested for 50 consecutive crizotinib naïve PBS patients.
- Obligations to inform oncologists on data collection.
- The new data was requested within 2 years.
- The PBAC considered the additional evidence at its March 2017 meeting.
- The additional data indicated a survival of 70% at 12 months which was consistent with trial data.
- No additional rebate was required and the terms of the agreement were met.

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Case Studies – financial risk share

Botulinum toxin type A for the treatment of chronic migraine.

- The PBAC was concerned use beyond the listed indication and a financial risk-share was requested.
- The PBAC considered a submission in March 2018 to change the caps of the risk-share arrangement that also included clinical evidence from a retrospective chart review.
- One of the PBAC's sub-committee's found that utilization was greater than predicted.
- The PBAC rejected the submission.

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Summary

- Risk share arrangements are common in Australia covering medicines that were recommended by the PBAC on a cost-minimization basis as well as cost-effectiveness basis.
- Risk share arrangements are used to manage certain risks or uncertainties with a new medicine.
- Risk share arrangements may help the payer contain certain risks such that a new medicine can be made available to patients.
- The majority of risk share arrangements are likely to be financial based agreements.
- These types of risk shares can help reduce the uncertainty regarding utilization for new medicines.
- Outcomes based risk share arrangements are less common.

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Summary

- Legally binding deeds of agreement are used to manage risk share arrangements.
- These can be a burden to sponsors given the limited scope for negotiation especially for class caps and/or pre-existing deeds.
- Most deeds last for 5 years after PBS listing. Sponsors need to consider implications for renegotiation if the Government decides to continue the risk-share arrangement.
- More complex outcomes based risk share arrangements involve costs to set up collection of data.
- These costs are borne by the sponsor.
- Medicines Australia was directly involved in policy discussions for the more recent managed entry schemes.
- Consumers and the industry association should be involved in future policy development around risk-share arrangements.

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