Engaging different stakeholders' views in HTA in Australia

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Australia

Who are the stakeholders?

- In Australia's NMP, stakeholders are described as "partners which need to enact their part of progressing the objectives of the Policy in a manner which is both cognisant and respectful of the interrelationships and expertise of other partners"

Stakeholders

- CONSUMERS
- Carers and families
- Society at large
- Consumer Organisations
- Sponsors of technologies
- Health practitioners
- Governments/Third Party Payers
- Health Educators
- Media

Value and Value for Money

- What constitutes value?
- In whose eyes is the value? ie value is in the "eye of the beholder" and may depend on context and time.
- Is "value" the same as "value for money"?

Example; I can afford to spend $200 million

- Is it better to spend the $200 million annually for a drug which has a median increase of survival (determined by extrapolation) of 4 weeks for a cancer, with a prevalence of 2500, for which there is no effective therapy . This drug has been deemed to target a newly identified biological marker of tumour progression. The cost/QALY is $100,000

or

- for that money to be spent on the improvement of palliative care services or some national screening program ?

or

- To spend the money somewhere else in the health system which might improve the lives of 10,000 people

In a perfect world we would say all of the above but rationing of services is likely because of resource constraints

Are there other options?

Compromise;-a not uncommon outcome

Spend $100million on both the drug and palliative care services ie reduce the total expenditure of each option

BUT

Who gets the medicine or service and who is denied?.

What criterea are used-those with families, younger?

Who makes that decision?

For those denied access can they buy it out of pocket-only for those who can afford $80,000

What are the ethical considerations?

Would your decision be influenced if a family member had the disease?

Scenarios

- Each one of these scenarios requires specific inputs from various stakeholders and there will be no one definite answer
- While all stakeholders have the right to input , in the end a JUDGEMENT will need to be made which weights various values and that will be dependent on a wide range of factors including the structure of the decision maker(s),social, cultural and religious factors as well as many other determinants

What is value?

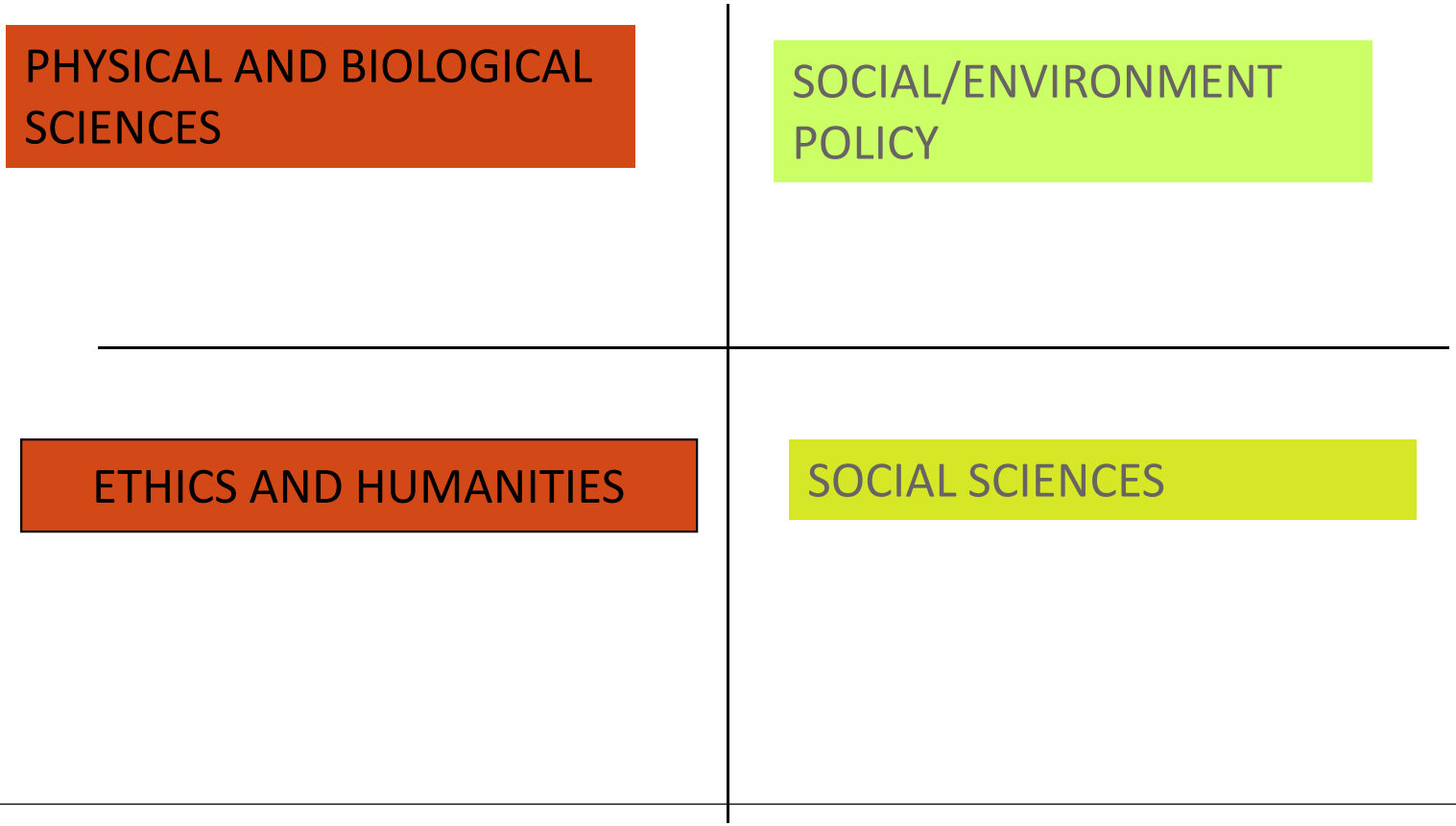
- Health benefit to patient

Non-Health benefit to patient

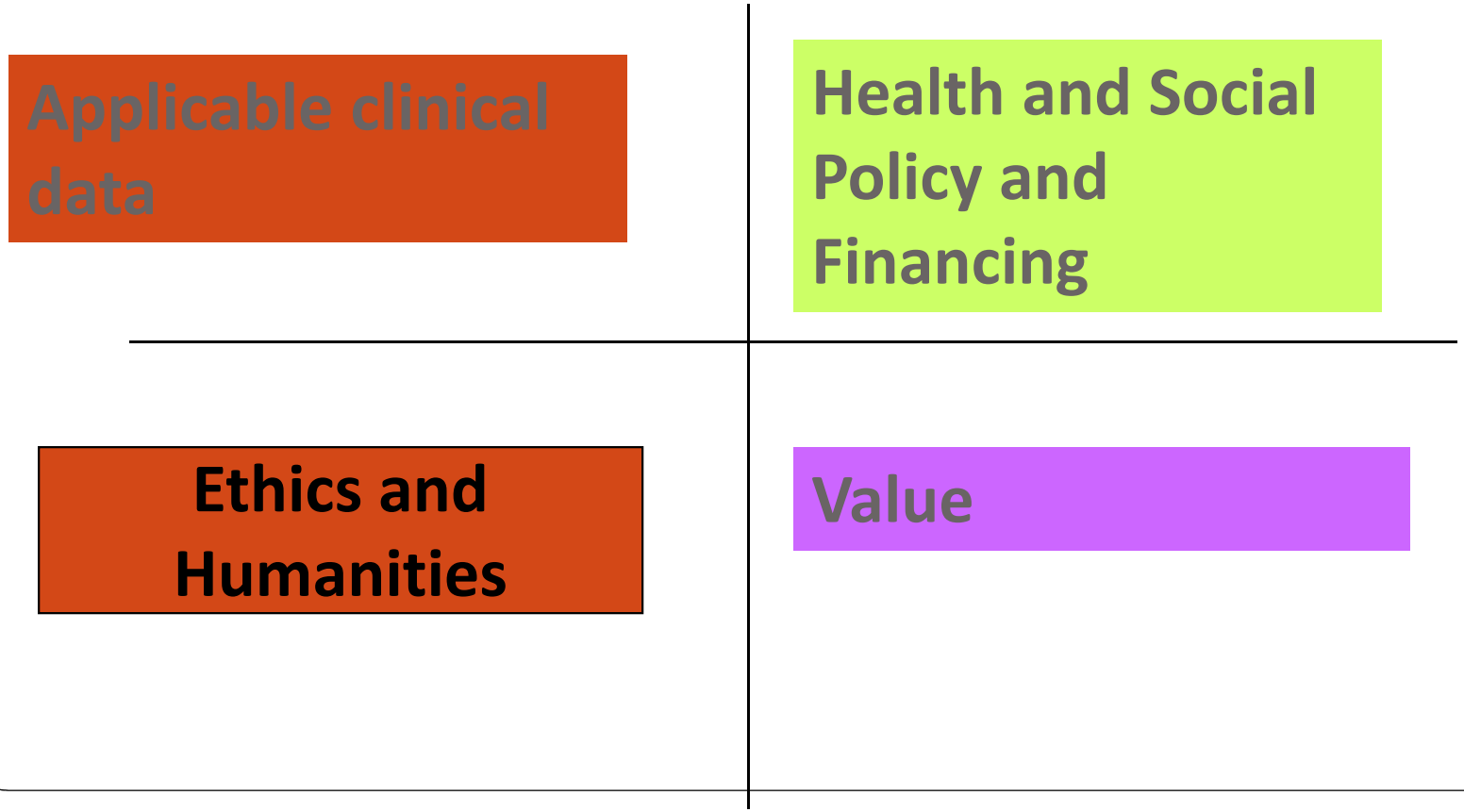
Benefit to carers and family

Benefits to Society, Health and Social Care System

CONSILIENCE – THE KEY TO UNIFICATION *(Wilson E O 1998)*



HTA CONSILIENCE *(Sansom 2013)*



What is HTA?

"HTA involves the medical, social, ethical and economic implications of the development, diffusion and use of a health technology. HTA has been positioned as a 'bridge between scientific evidence and the needs of policymakers"

HTAi definition of HTA

- *A research-based ,practice-oriented assessment of relevant available knowledge on the direct and intended consequences of technologies ,as well as the indirect and unintended consequences.The goal of health technology assessment is to provide input to decision making in policy and practice*

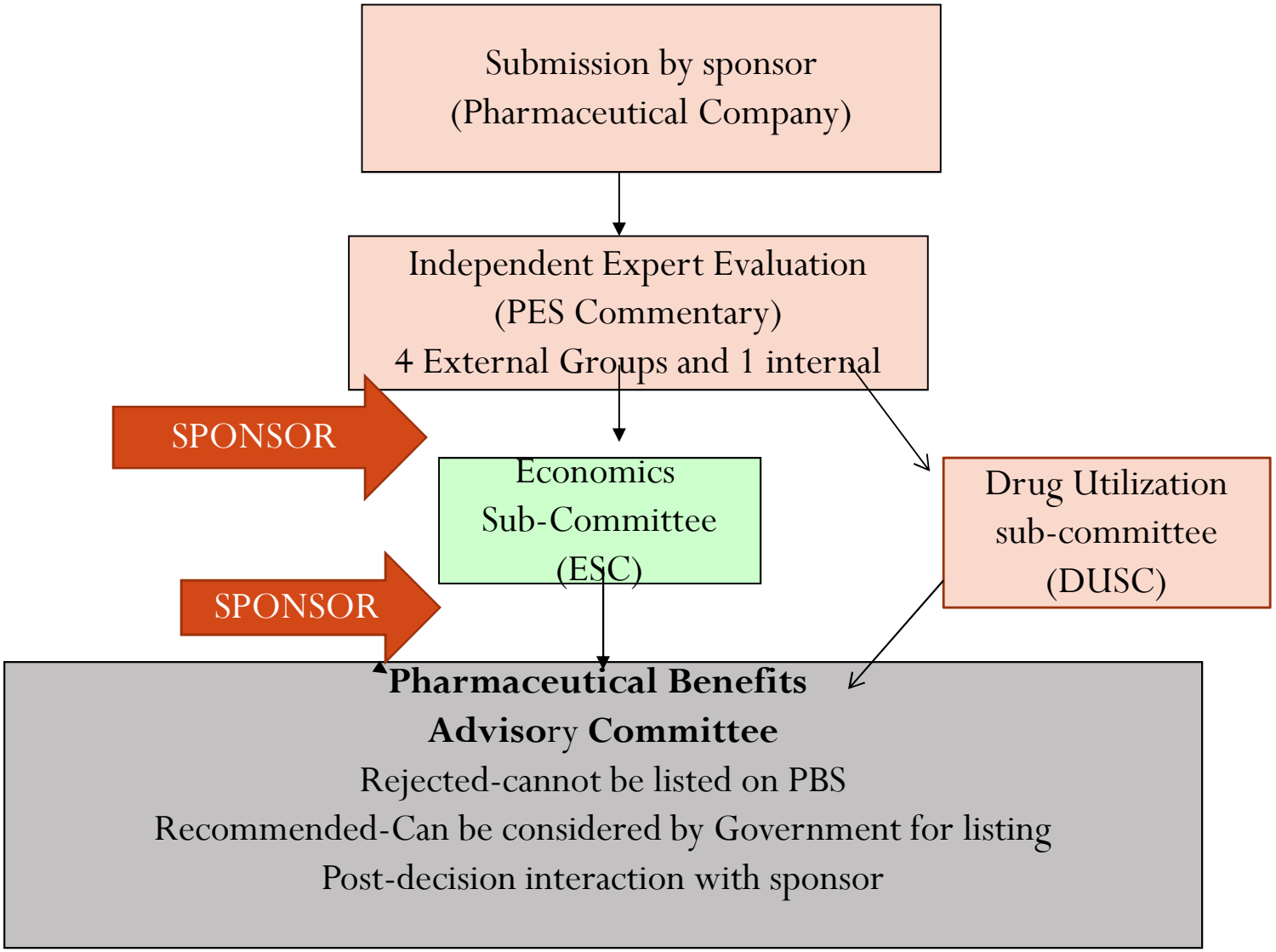
HTA Advisory Committees in Australia

- PBAC-Pharmaceutical Benefits Advisory Committee
- ACPM-Advisory Committee on Prescription Medicines
- MEC-Medicines Evaluation Committee(non-prescription)
- CMEC-Complementary Medicines Evaluation Committee
- MSAC-Medical Services Advisory Committee
- Stoma Assessment panel
- Prosthesis evaluation group

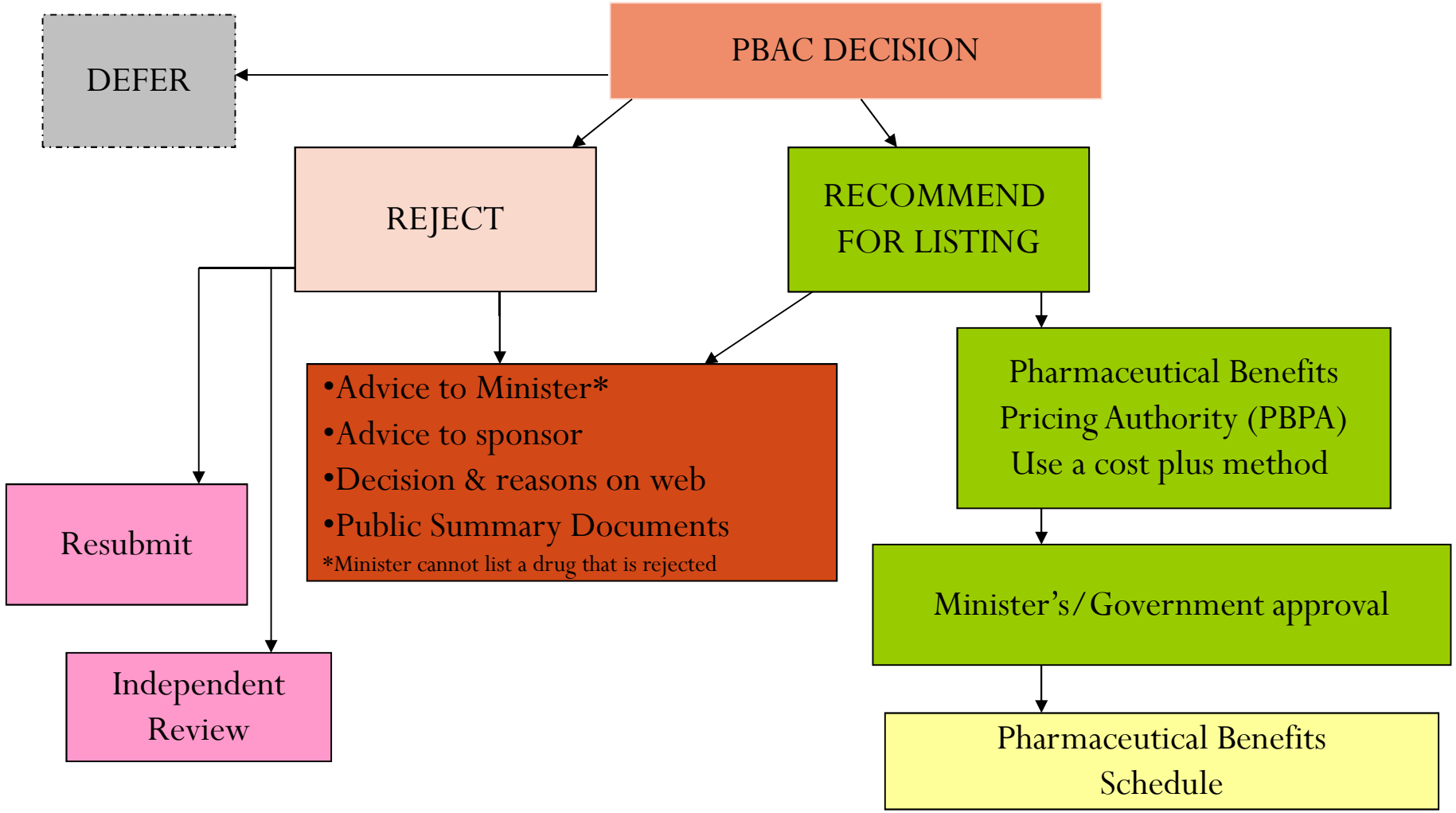
The Australian Scene for Pharmaceuticals

- The Health technology assessments are undertaken by contracted external agencies usually upon receipt of a submission prepared by sponsors in accordance with guidelines for submissions
- Generally single technology appraisals
- More recently the Government has initiated a number of reviews eg anticoagulants in AF, Anticholinesterases in dementia, management of paediatric asthma, and management of type 2 diabetes. The reviews are commissioned by external xperts and stakeholders respond

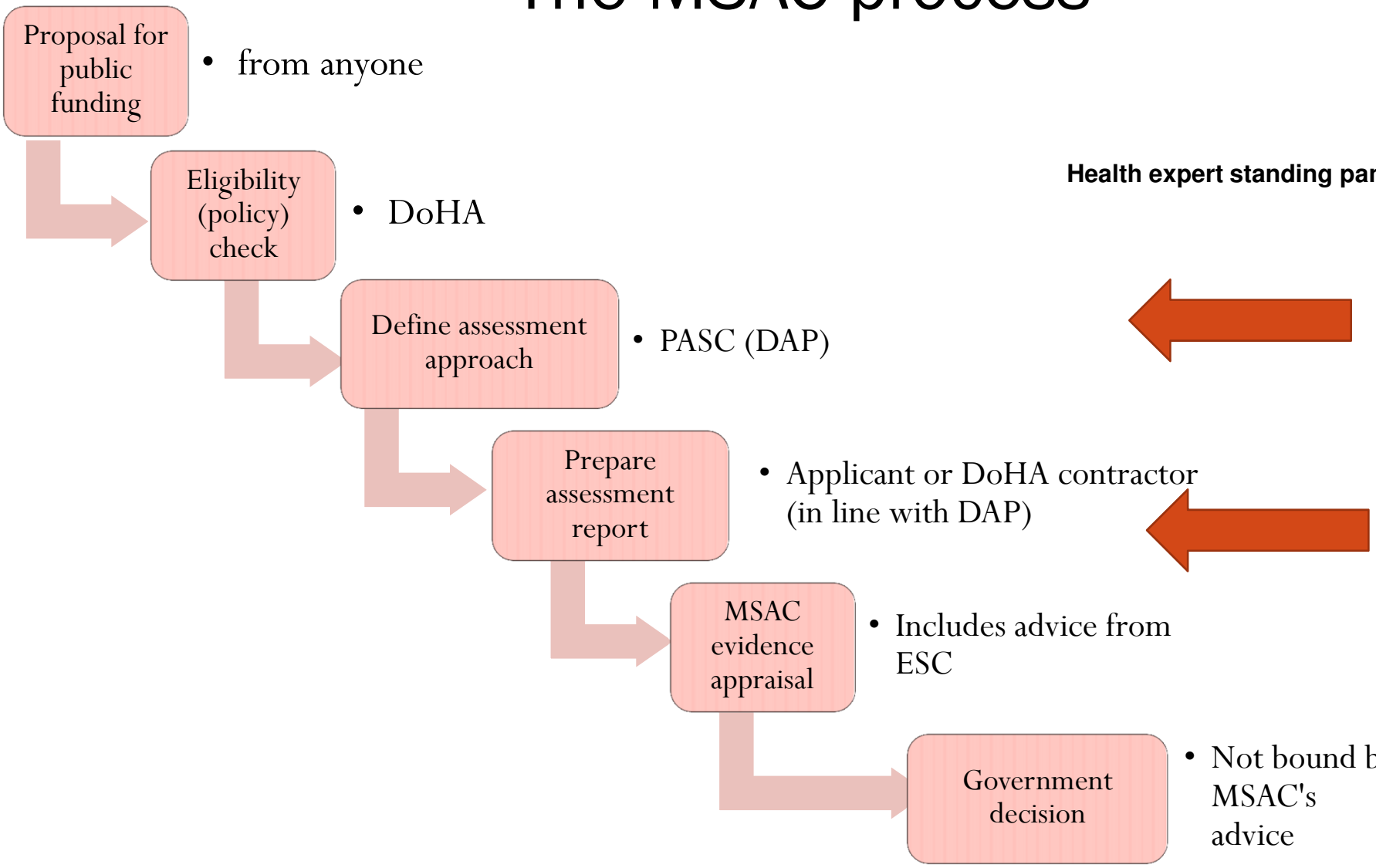
Process for Pharmaceuticals listing : 17 week cycle



Process for listing 2: Post PBAC



The MSAC process



Sponsors

- Normally undertake clinical trials to determine the health benefit to the patient
- Often the data generated from these trials need to be translated to patient relevant outcomes eg use of surrogate outcomes, applicability of the trial results to the local context/any requested restriction to subsidy

Sponsors

- Sponsors need to interact with patients before trials to ensure that patient relevant outcomes are measured in the clinical trial eg quality of life, activities of daily living .Failure to do so inevitably ends up in issues regarding the relevance of the trial data to HTA.

Interaction between sponsors and HTA decision makers-options

- Early dialogue regarding the requirements of HTA agencies in relating to trial issues
- In Australia this has occurred on occasions but is rare and adhoc
- Tapestry(Europe) and NICE have formal processes for early dialogue

Interaction between sponsors and HTA decision makers-options

- Pre-submission meetings between sponsors and HTA agencies. This occurs with most submissions in Australia
- Opportunity for a hearing before the PBAC –(10minutes)- may bring patient /patient representatives
- Post decision meetings with decision maker to discuss reasons for rejection and ways to move forward with any future submission OR to negotiate a price which may address uncertainty. This occurs routinely in Australia

Patients-Interaction

- Consumer member on the PBAC as a full voting member
- On-line input from consumers (and others). This occurs for every meeting
- Specific requests to patient groups eg "consumer impact statements" for certain conditions eg social anxiety disorder ,upper limb spasticity following stroke. This are limited
- Consumer juries have not been established along the NICE model

On-line inputs

- "A list of the applications for consideration at each Pharmaceutical Benefits Advisory Committee (PBAC) meeting is published six (6) weeks prior to each meeting. The Agenda for the PBAC meeting can be found on the PBS website.

  Your comments are welcome whether you are a patient, carer, member of the public, health professional or member of a consumer interest group."

On-line inputs

- All comments received will be considered. Issues from individuals will be made available in summary to the sponsor of the application and the PBAC. The names of individuals will be removed. All comments from groups or organisations will be provided in a complete form to both the PBAC and the sponsoring organisation.

  To complete the consumer input form, please go to the PBAC online submission form. When you have completed the form and pressed the SUBMIT button, your form will be sent electronically to the PBAC Secretariat and you will receive email confirmation of receipt which will include a copy of your comments. This form is also available in hardcopy on request from the PBAC Secretariat on (02) 6289 7099.

On-line inputs

- What treatment (if any) are you using now?

-please describe what medicines you take to treat your health problem and how well this treatment works

- What do you see as the benefits of this new medicine for you?

-Please describe the benefits you think the new medicine could have on your health? Do you think the new medicines will have any disadvantages

On-line inputs

- How will your life and that of your family and carers by improved by this new medicine?

-Please describe how you think this medicine will affect your life and the lives of your family and carers. Please explain why you think this

- What other benefits can you see from having this medicine on the PBS?

-Please describe any other benefits you think will come from having this medicine listed on the PBS (for example:fewer hospital visits, reduced time off work and so on)

- Do you have any comments on the consumer input process

Patient/Carer inputs

- While the on-line inputs have proved popular there is a need to assist consumers to improve the process. Currently a group consisting of a PBAC member, a Government officer, sponsor represenative and consumer representatives are discussing ways to achieve this improvement.
- This has been hampered in the past by sponsors being reluctant to disclose when a submission has been received by the PBAC-hence the current release of agenda 6 weeks prior to the PBAC meeting which is often too late for consumers to provide an effective input

Professional Groups

- Formal meeting with the Medical Oncology Group annually.
- Regular meetings of the PBAC chair with representatives of clinical specialities
- Many talks at professional Associations Conferences re process
- Stakeholder meetings held from time to time to address area of clinical uncertainty regarding listing or restriction eg life saving drugs program, bDMARDs in RA, anticoagulants in AF. Expert Clinicians involved as well as consumers and sponsors

The Benefits to Society, Health and Social Systems

- These factors are often considered in the context of cost offsets in the analysis of cost effectiveness eg reduction in hospital/medical care costs, impact of vaccinations on society.
- However consideration of other benefits eg productivity gains may be problematic and introduce inequity issues.
- The role of innovation and the "hope" a technology offers to the future is difficult to manage particularly in the presence of a small health gain, a promise of potential gain ,but in the context of constrained budgets which raises issue of opportunity costs

Wilson-1998 Was he thinking about HTA?

- "We are drowning in information while starving for wisdom. The world henceforth will be run by synthesizers, people able to put together the right information at the right time, think critically about it, and make important choices wisely"