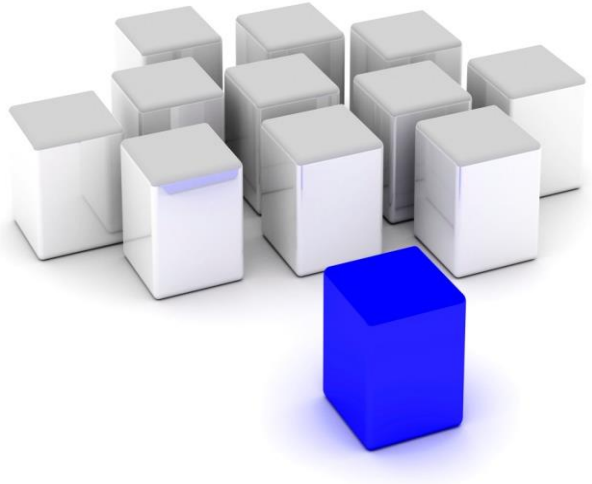

Patient Voice Initiative

HTA in Australia for listing new drugs on the PBS: What, Who and How

Ian Noble

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rare cancers AUSTRALIA

CaPPRe

Overview

- What is HTA
- Who makes the decisions – PBAC and what they consider
- How does the process work in Australia
- What is the consumer role

What is Health Technology Assessment (HTA)?

"a form of policy research that examines short- & long-term consequences of the application of a health-care technology. Properties assessed include evidence of safety, efficacy, patient-reported outcomes, real world effectiveness, cost & cost-effectiveness as well as social, legal, ethical, & political impacts"

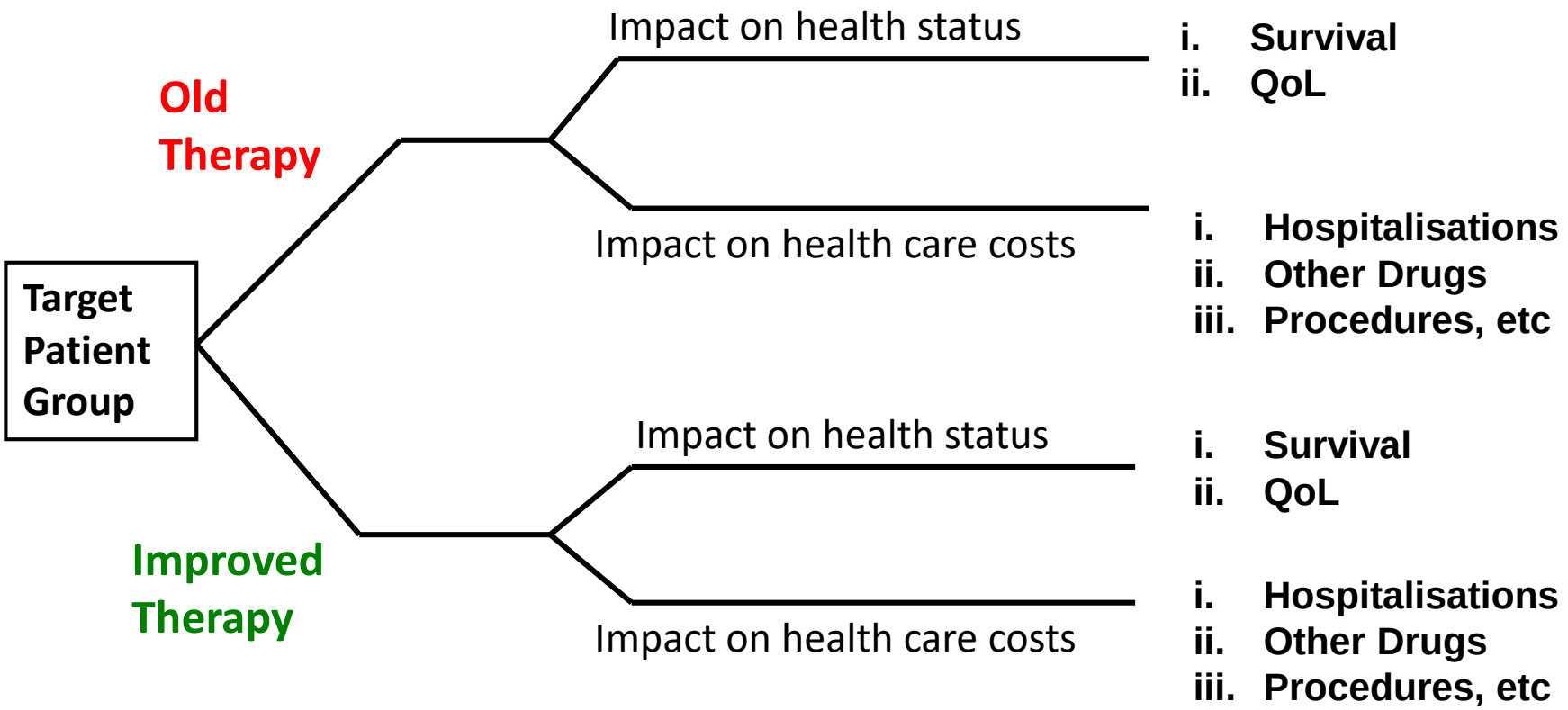
- International Society For Pharmacoeconomics & Outcomes Research's (ISPOR)

A comprehensive weighing up of pros and cons to aid decision making

Why is HTA used by the Australian Government

- Resources are scarce
- Health care needs (and wants) are potentially unlimited
- Rationing / prioritisation is necessary
- Decision makers need to consider OPPORTUNITY COST

HTA's always compare 2 or more treatments

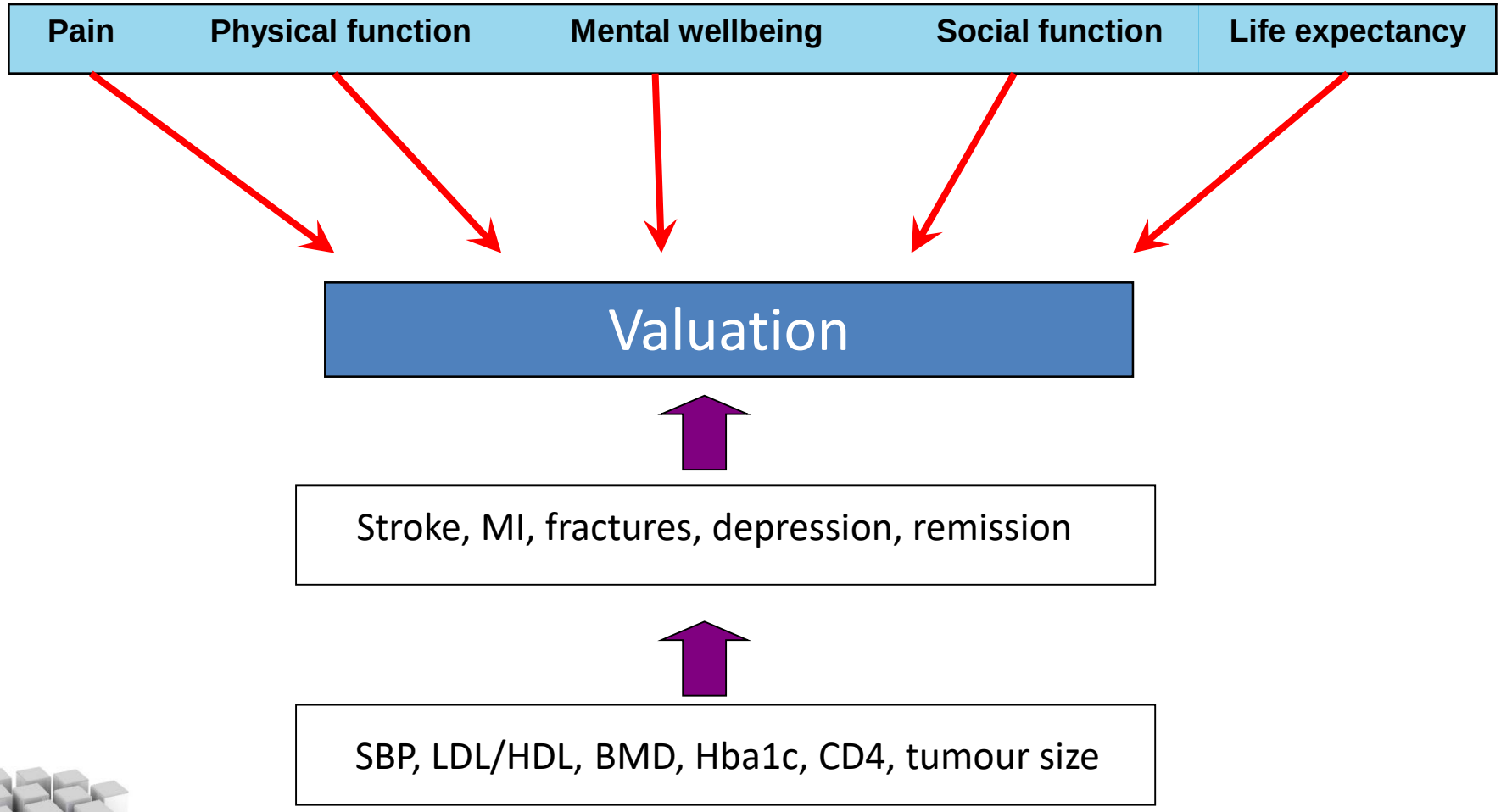


The main output is an “incremental cost effectiveness ratio” – an ICER!!!

	cost	Additional years of life
old therapy	$6,000	4yrs
improved therapy	$80,000	6yrs

Additional cost is $74,000 but we get an additional 2 years of life = $37,000 per life year gained

But there is more to life than time: Quality of life is vital and very complex to measure



Bringing it altogether - The Quality Adjusted Life Year (QALY)

- The QALY Combines two time and quality of life

- Our improved drug has significant side effects so the 2 additional years of life need to be discounted. In this case 2 additional years are transformed to 1.2 Quality adjusted life years

$74,000 / 2 years = $37,000 per life year gained

$74,000 / 1.2 = $62,000 per QALY

BUT, is $62,000/QALY considered good value for money????... we need the PBAC to answer this question

Who makes the decisions – PBAC and what they consider?

The PBAC makes a recommendation to the Minister of Health

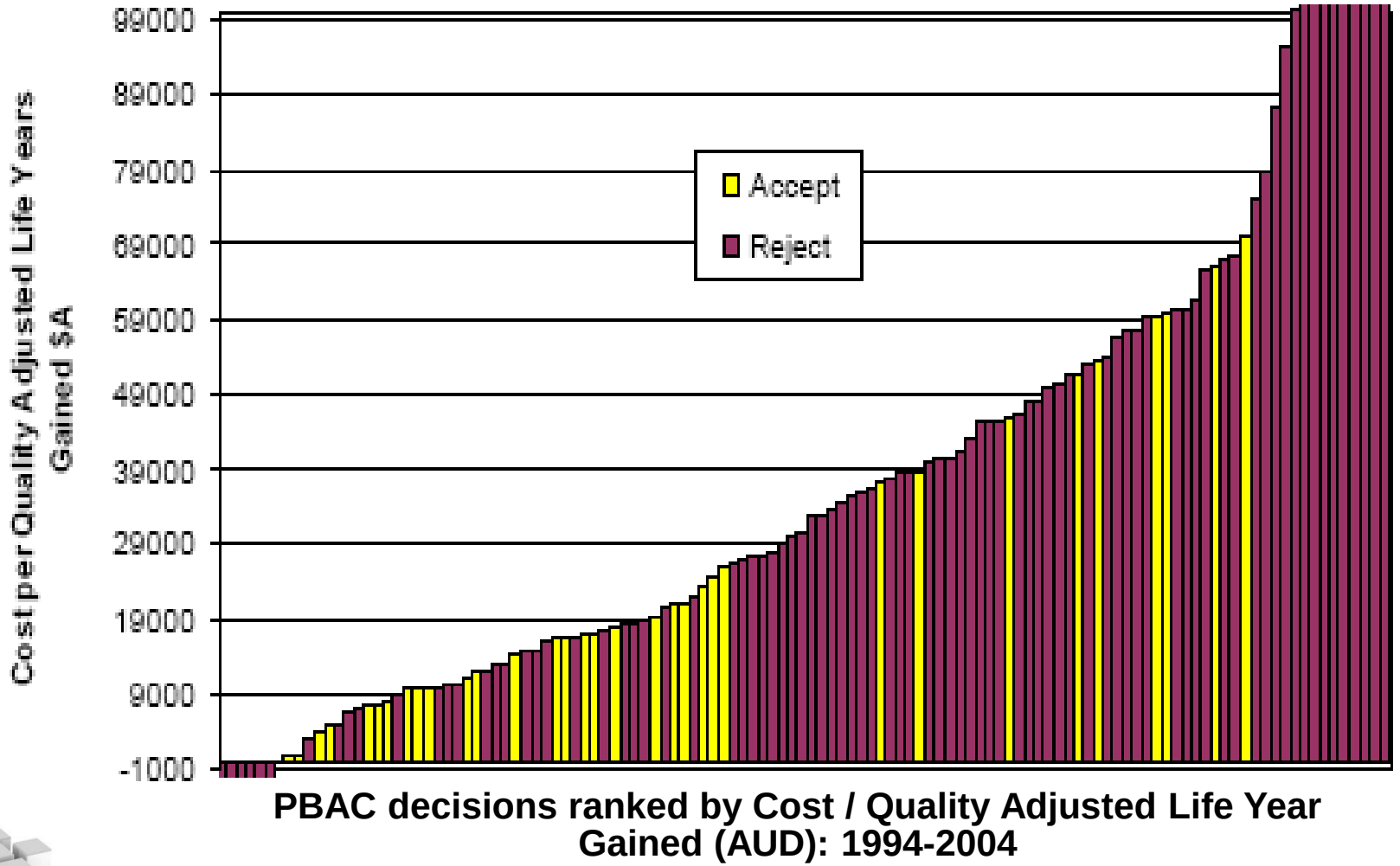
- National Health Act: Section 101, Functions of the Pharmaceutical Benefits Advisory Committee
  - (3A)…. The Committee shall give consideration to the **effectiveness** and **cost of therapy** involving the use of the drug, preparation or class, including by **comparing the effectiveness** and **cost of that therapy** with that of alternative therapies, whether or not involving the use of other drugs or preparations.
  - (3B) …. Without limiting… where therapy involving the use of a particular drug or medicinal preparation… **is substantially more costly than an alternative therapy or alternative therapies**, whether or not involving the use of other drugs or preparations, the Committee:
    - (a) Shall not recommend to the Minister that the drug, preparation or class be made available as pharmaceutical benefits under this Part unless the Committee is satisfied that the first mentioned therapy, **for some patients, provides a significant improvement in efficacy or reduction of toxicity over the alternatives…"**

The PBAC MUST follow the National Health Act

The PBAC

- Currently 16 members (going to 18)
- Nephrology, haematology, geriatric medicine, oncology, endocrinology, generla practicen pharmacy, rheumatology, consumer, health economist
- Professor Andrew Wilson is chair
- Jo Watson is the consumer rep – (recently joined by another consumer rep)
- Meet 3 times per year in either Adelaide, Sydney, Canberra, Melbourne or Brisbane
- Meet for 3 days at a time

Positive and negative PBAC decisions and the cost per QALY



The cost per QALY is the main factor but other factors are considered too in decision making

Important factors to consider

- Efficacy (& effectiveness) & safety
- Cost-effectiveness
- Budget impact
- Uncertainty
- Clinical need
- Equity
- 'Rule of rescue'
- Other difficult to quantify benefits of medicines
- Patient capacity to pay
- Incentive for current & future R&D

Challenge is to develop decision analytic framework to consider all factors in a systematic way

Snapshot of the March 2015 PBAC Meeting – Positive Major Submissions (Excluding vaccines)

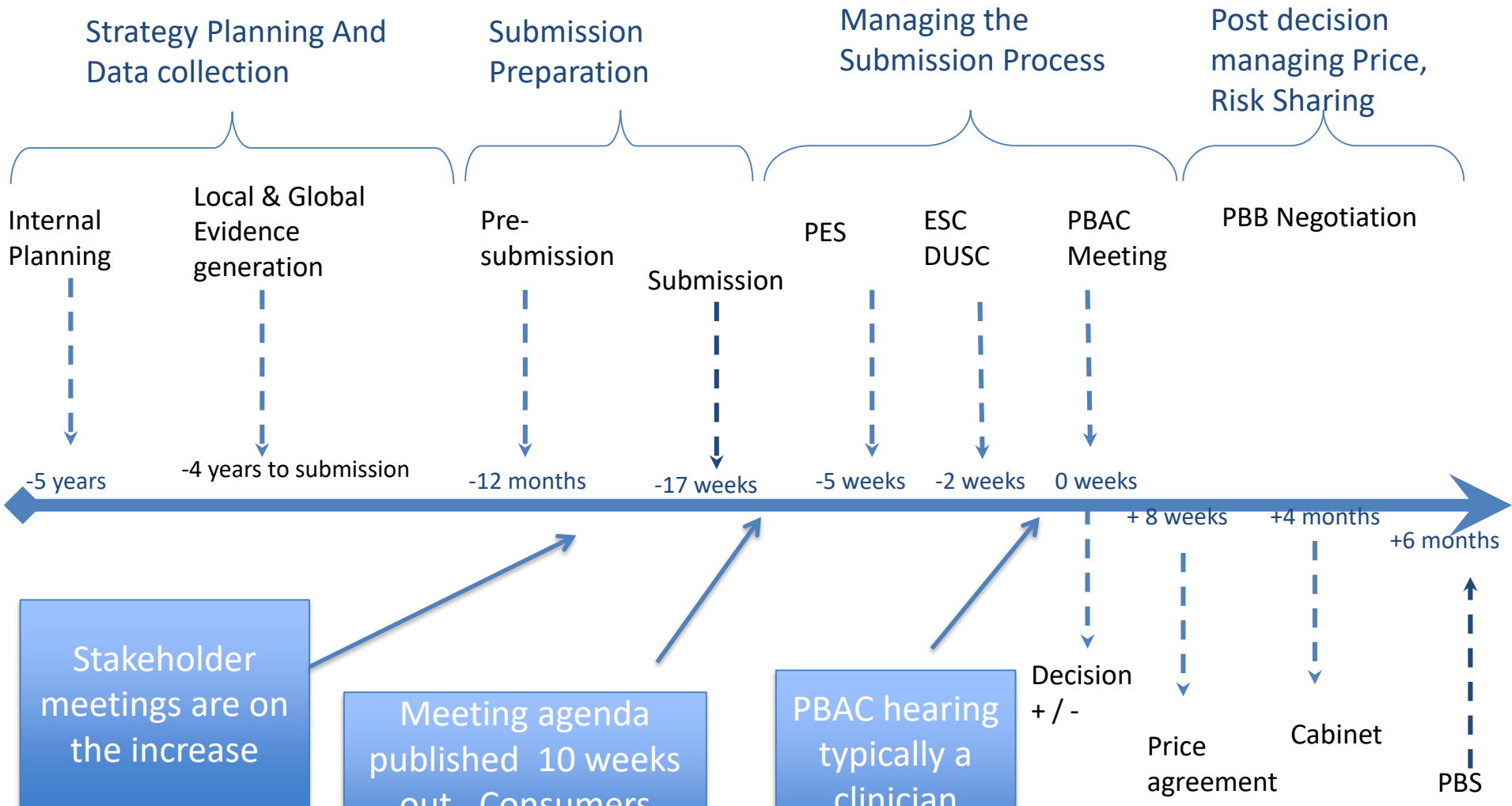
- 17 Major submissions that were positive
- 13 Submissions were for specialty medicines (high specialist involvement, complex diseases)
- 4 largely GP medications (diabetes, DVT, Gout)
- 7 submissions were granted CEA status

Most medications seeking reimbursement on the PBS are complex high cost medications (high cost per patient per year) – these attract extra PBAC scrutiny

- Lutropin (fertility) CMA
- Apixaban (DVT) CMA
- Canakinumab (juvenile arthritis) CMA
- Daclatasvir (HCV) CEA
- Ledipasvir/sofosbovir (HCV) CEA
- Sofosbovir (HCV) CEA
- Dapagliflozin (Diabetes) Cost analysis
- Exenatide (Diabetes) Cost analysis
- Febuxostat (Gout) CEA
- Lurasidone (schizophrenia) CMA
- Obinutuzumab (Lymphocytic Leukaemia) CEA
- Pembrolizumab (melanoma) CEA/MES
- Ruxolitinib (myelofibrosis) CEA
- Secukinumab (Plaque psoriasis) CMA
- Tofacitinib (Rheumatoid arthritis) CMA
- Vedolizumab (Crohn's disease) CMA
- Testostenone (Androgen deficiency) CMA

How does the process work and what is the consumer's role?

The process for gaining PBS access is rigorous and lengthy – it takes 5+ years including local evidence generation



However, there is a long way to go to factor the consumer view into the heart of decision making

- PBAC submissions are pretty much done deals by the time consumers know about it (10 weeks prior the PBAC meeting)
- The DOH does not systematically seek consumer views – its simply a website with a form at the moment
- Up until now the PBAC committee has been dominated by clinicians

The world of consumers and the PBAC are different

- The PBAC is interested in minimizing bias – they like:
  - Systematic processes
  - OBJECTIVE health related scientific data (eg blood pressure, lipid levels et)
- Consumers are often more interested in different types of evidence and approach:
  - Tends to be narrative/descriptive and the process is ad-hoc
  - SUBJECTIVE outcomes often difficult to measure (eg choice, freedom from pain and anxiety, being able to work/study)

The PBAC needs to learn the language of the consumer and the consumer needs to appreciate the need for robust HTA

Summary

- HTA is neither good nor bad – it's a useful tool for good decision making
- The PBAC relies on HTA to make decisions – it's a very robust process
- The whole process however is not good at factoring in the consumer view and the richness of information that can bring
- The Commonwealth and PBAC are trying hard to improve this
- An educated consumer voice will help signal to Government, clinicians and industry the importance of consumer preferences
- Bringing the two worlds together will help strengthen the PBS for Australia

Questions