REGISTERING A MEDICINE
USUALLY TAKES 11 MONTHS

PBAC ASSESSMENT
USUALLY TAKES 4 MONTHS

PBS LISTING
TAKES A MINIMUM OF 4 MONTHS

R&D

1

Submit regulatory dossier to TGA

ACPM considers data on Quality,Safety and Efficacy

APPROVAL

Approval – Australian Register of Therapeutic Goods (ARTG)

3

SUBMIT PATIENT VIEWS

Consumers

5

HEARING

REJECT

RE-SUBMISSION

PARALLEL PROCESSING

NON-PARALLEL PROCESS

Submit to PBAC

2

Submit to PBAC

PBAC considers submission

Recommend

Price and listing negotiation

4

Approval by the minister (and if required cabinet)

PBS

PBS

ABOUT PBAC SUBMISSION

Types	Request
Major	New listing
Minor	Changes to current listings (e.g forms, restrictions)
Re-submission	Like a major submission
Secretariat/ PEB	Listing of generic medicines

ABOUT MEDICINES RESEARCH

Basic research & drug discovery. Preclinical trial on non - human subjects. Clinical trials on human subjects.

- Phase 0: Test how medicines are absorbed, distributed in the body, metabolised and eliminated from the body
- Phase 1: Trying to find the range of safe doses in healthy subjects
- Phase 2: Testing safety and tolerability (and efficacy) in patients
- Phase 3: Testing efficacy effectiveness and safety in patients

HOW PBAC CONSIDERS A SUBMISSION

Comparative assessment

Drug A — Equal — New Med = **Same Price**

Drug A — Better — New Med = **Higher/lower price corresponding to:**

- Relative UP or DOWN in health benefits
- Government's "ICER" threshold

Drug A — Worse — ⊘ = **Evidence not certain**

- Managed Access Program (MAP)

Decision making criteria

- QUANTIFIABLE

Clinical

Need

Efficacy

Cost-Effectiveness

Budget Impact

- LESS QUANTIFIABLE

- Confidence in clinical evidence and modelling assumption
- Equity concerns
- Severity of conditions
- Public health concerns
- Quality use of medicines
- Suitability of the medicines being listed on the PBS

COMPONENTS OF THE PBS

Programs

- General schedule medicines
- The Highly Specialised Drugs Program
- The Efficient Funding of Chemotherapy program
- The Botulinum Toxin Program
- The Growth Hormone Program
- The IVF Program
- The Opiate Dependence Treatment Program
- [Life Saving Drugs Program]

Programs

- Formulary 1: Single brand, usually on patent
- Formulary 2: Multiple brands, usually off patent
- Combination drug list: on & off-patent components

Incremental cost - effectiveness ration or ICER

Differences in costs of A vs B
Differences in benefits (e.g. QALY) between A and B

Criteria for MAP

- High and urgent unmet clinical needs
- PBAC would NOT otherwise recommend the listing because of uncertainty or high cost
- Evidence can reliably be reported and evaluated within a reasonable timeframe (i.e. real world evidence).