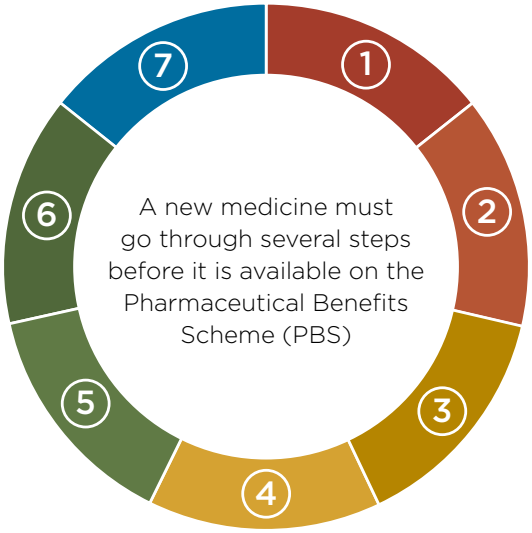
Bristol-Myers Squibb

Guide to Accessing Cancer Medicines in Australia – An Overview

FROM DISCOVERY TO ACCESS – HOW CANCER MEDICINES REACH PATIENTS



1. PRE-CLINICAL RESEARCH: 4 years on average to develop a new molecule[1] before it becomes a medicine.

2. CLINICAL TRIALS: 9 years on average[2] to take a promising new molecule from the lab through carefully controlled clinical trials.

3. REGISTRATION: Pharmaceutical companies must apply to the Therapeutic Goods Administration (TGA) for approval to market (sell) the new medicine in Australia.

4. RECOMMENDATION: A new cancer medicine must be evaluated for cost-effectiveness by the Pharmaceutical Benefits Advisory Committee (PBAC) before it will be recommended for listing to the Australian Government.

5. MINISTERIAL OR CABINET REVIEW: PBAC recommendations are reviewed by the Australian Government and a decision is made whether to make it available (and affordable) to patients through the PBS.

6. PBS LISTING DATE: The Health Minister decides when new medicines will be added to the PBS.

7. NEW USE: If clinical trials suggest a medicine is effective in treating another type of cancer (known as a new indication), this process begins again.

HOW DO CLINICAL TRIALS WORK?

- In a clinical trial, new cancer medicines are usually compared to something else, known as a 'control'. This can be a placebo (which contains no medicine) or a treatment already in use (usually the current standard of care).
- 'Gold standard' clinical trials (often considered the most reliable) are when patients are randomly assigned to two or more groups and where neither patients nor researchers are aware of which group a patient has been assigned to.
- If you are interested in participating in a clinical trial, you should speak with your doctor about your options. You could also visit: http://www.australianclinicaltrials.gov.au/consumers/how-find-clinical-trial

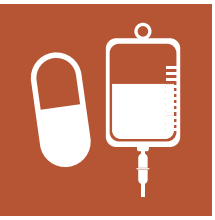
Clinical trials of new medicines typically go through four phases.[3]

PHASE I	Tests a new medicine for the first time in a small group (20-80 people) to evaluate safety, including dosage and side effects.	20-80 · EVALUATE SAFETY · SAFE DOSE
PHASE II	Tests a new medicine in a larger group of people (up to several hundred) to determine whether the medicine works as it should (efficacy) and further evaluate safety.	200+ · EFFICACY · EVALUATE SAFETY
PHASE III	Tests efficacy of a new medicine in large groups of people, comparing the new medicine to other treatments - as well as additional safety information.	LARGE GROUPS · COMPARE · COLLECT INFO
PHASE IV	Takes place after a medicine has been approved. These studies monitor the effectiveness of the approved medicines in the general population and collect information on side effects that may emerge with widespread use over time.	MONITOR · USE OVER TIME

1. Mark E Bunnage, Getting pharmaceutical R&D back on target. Nature Chemical Biology, Vol 7, June 2011, p335
2. Ibid
3. Australian Government National Health and Medical Research Council Department of Industry and Science: Australian Clinical Trials – Phases of clinical trials, Accessed August 7, 2015. Available at: http://www.australianclinicaltrials.gov.au/what-clinical-trial/phases-clinical-trials

HOW IS A CANCER MEDICINE APPROVED FOR USE IN AUSTRALIA?

- All medicines marketed for human use must be registered with the TGA and listed on the Australian Register of Therapeutic Goods (ARTG): https://www.tga.gov.au/australian-register-therapeutic-goods
- The TGA registration and approval process can take up to 12 months.
- More information about the TGA and its processes can be found at https://www.tga.gov.au/



WHAT IS THE PBAC, WHAT IS THE PBS, AND HOW CAN CANCER PATIENTS GAIN ACCESS TO MEDICINES IN AUSTRALIA?

- The PBAC makes recommendations to the Government about whether to list new medicines on the PBS, based on clinical benefit and cost-effectiveness.
- The PBS provides affordable access to medicines for patients who need them.
- A medicine must be approved by the TGA for a specific use (known as an indication) before it can be listed on the PBS for that use.

CAN PATIENTS HAVE A SAY IN THE PBAC REVIEW PROCESS?

- Anyone who is interested in a particular medicine and the decision on whether it should be subsidised (listed on the PBS) can have their voice heard.
- Organisations and individuals can access the consumer comment form through the Department of Health website: http://www.health.gov.au/internet/main/publishing.nsf/Content/PBAC_online_submission_form

WHAT HAPPENS AFTER THE PBAC MAKES ITS RECOMMENDATION?

- The Health Minister considers the PBAC's recommendation, as well as advice from the Department of Health on the cost of the listing on the PBS - which is determined following negotiations with the sponsor (pharmaceutical company).

HOW CAN A PATIENT GET ACCESS TO A MEDICINE PRIOR TO TGA REGISTRATION OR LISTING ON THE PBS?

- Prior to registration with the TGA, most medicines are not available to patients.
- In certain cases, a Special Access Scheme can be used. This allows doctors to request an unapproved medicine on behalf of their patient, once the patient has exhausted all other approved treatment options. More information can be found on the TGA website: https://www.tga.gov.au/form/special-access-scheme
- Some pharmaceutical companies also offer Patient Access Programs for medicines that are registered with the TGA, but not yet listed on the PBS. Patient Access Programs are only available to eligible patients, and there may be a cost to patients. Only doctors can request the medicine on behalf of their patient. Pharmaceutical companies in Australia are guided by the Medicines Australia Code of Conduct and are limited in what information they can share directly with patients about these programs.

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