

7.1 Generic testing

Innovator brand	Comparator
The brand name of the original patent holder for the drug <ul style="list-style-type: none">• Start with a capital letter	The International Non-proprietary Name (INN) - the name of the active ingredient <ul style="list-style-type: none">• Lowercase letter• Some manufacturers use brand names too

Significance of generic medications

If a medicine is listed on the PBS:

The patient pays a co-payment and the government pays the remainder

- If item cost is lesser than co-payment amount, there is no government contribution

Patient pays brand price premium if innovator (original) brand chosen

- Check the PBS. Not all innovator brands are more expensive than generics

Total cost includes: - a wholesale mark-up

- Professional service fees (dispensing fee, administration handling and infrastructure fee) *fixed, indexed
 - As a core pharmacy service under traditional model, this is how the pharmacy and the manufacturer make a profit
- The manufacturer and the government bargain arrangements

The price of an original brand will have a 16% mandatory reduction on the total cost when a generic alternative is approved. The consumer pays for the brand (brand-price premium). With generics both, the government and the consumer pay less.

Requirements of a medication to be registered as a generic medication

Generic products must be bioequivalent to the innovator brand product/ the market leader before they are approved in Australia.

Bioequivalence – comparable bioavailability (rate and extent of absorption of drug into the systemic circulation)

- Same active ingredient
- Same dose – USUALLY (some exceptions e.g. perindopril erbumine 2mg and arginine 2.5mg)
- Same dosage form and route of administration, e.g. IR vs SR
- Usually similar dissolution performance etc
- Not necessarily same excipients
- Not necessarily the same colour
- Sometimes out of the same factory