Medicine regulatory bodies and instruments in Australia

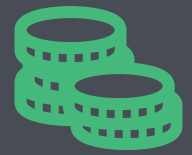
Australian Department of Health

Poisons standard
– Classifies drugs

State/territory legislation and regulatory control bodies

Therapeutic Goods Administration
– Regulates what can be lawfully supplied
– Monitors product safety

Pharmaceutical Benefits Advisory Committee
– Recommends PBS listings



Pharmaceutical Benefits Scheme
– Subsidises medicine costs

Click on an underlined body or instrument for more information

MDA National

Poisons Standard – 1

- Classifies poisons (including medicines) into 10 schedules of various availability control levels
  - To protect public health and safety
- Decision-maker = Department of Health Secretary (or their delegate)
- Implemented through state and territory legislation
  - State/territories rarely vary their classifications from the Poisons Standard

www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals

MDA National

Poisons Standard – 2
Schedule 8

- “Controlled drugs”
- Greater healthcare professional involvement
- Stricter availability restrictions
- Each state/territory has own Schedule 8 medicine prescribing requirements
- Doctors need to apply for a Schedule 8 prescription permit from the health department in their state/territory in some circumstances

www.tga.gov.au/book/export/html/288973

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MDA National

Therapeutic Goods Administration (TGA):

- Regulates supply, manufacture and advertising of therapeutic goods in Australia
  - Medicines, biologicals and medical devices
  - Oversees the Australian Register of Therapeutic Goods (ARTG)
- Evaluates the quality, safety and effectiveness of all medicines available for supply in Australia
- Operates within the federal Department of Health

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www.tga.gov.au/what-are-therapeutic-goods, www.tga.gov.au/medicines-and-tga-classifications

Australian Register of Therapeutic Goods

- If the TGA grants a “higher risk” therapeutic good market authorisation, it is entered on the ARTG
- Only medicines that are “registered” or “listed” on the ARTG “… may be supplied in or exported from Australia, unless exempted”
- All prescription medicines are “registered” on the ARTG

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www.tga.gov.au/how-tga-regulates, www.tga.gov.au/medicines-and-tga-classifications

MDA National

Pharmaceutical Benefits Advisory Committee

- Independent body, appointed by the Australian Government
- Primary role = "… recommend new medicines for listing on the PBS"
- Can be doing its reimbursement and assessment processes in parallel while a product is going through TGA processes

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www.pbs.gov.au/info/industry/listing/participants/pbac

MDA National

Pharmaceutical Benefits Scheme (PBS) – 1

- Commonwealth initiative
  - Within Department of Health
- Makes medicines for most conditions affordable

- If a medicine is cost-effective then the government negotiates price with supplier

- PBS prescribing regulated under *National Health Act 1953* (Cth)
- Strict rules for prescribers

www.pbs.gov.au/info/about-the-pbs

MDA National

PBS – 2

PBS Schedule has three categories:

1. Unrestricted benefits = no restriction on therapeutic use
2. Restricted benefits = “can only be prescribed for specific therapeutic uses”
3. Authority required benefits = restricted benefits, need prior approval from Services Australia/Department of Veterans’ Affairs
    i. Authority required – by phone/online
    ii. Streamlined Authority = electronic authority code

www.pbs.gov.au/info/about-the-pbs, www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/pbs-prescribers/resources/request-authority-using-online-pbs-authorities-hpos

MDA National

- PBS authority requirements are **separate** to state/territory Schedule 8 prescribing permits
- Prescribers may need to apply for **both**

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