

Appealing TGA Decisions & Navigating Section 60 Reviews for Devices and Medicines

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Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

tga.gov.au



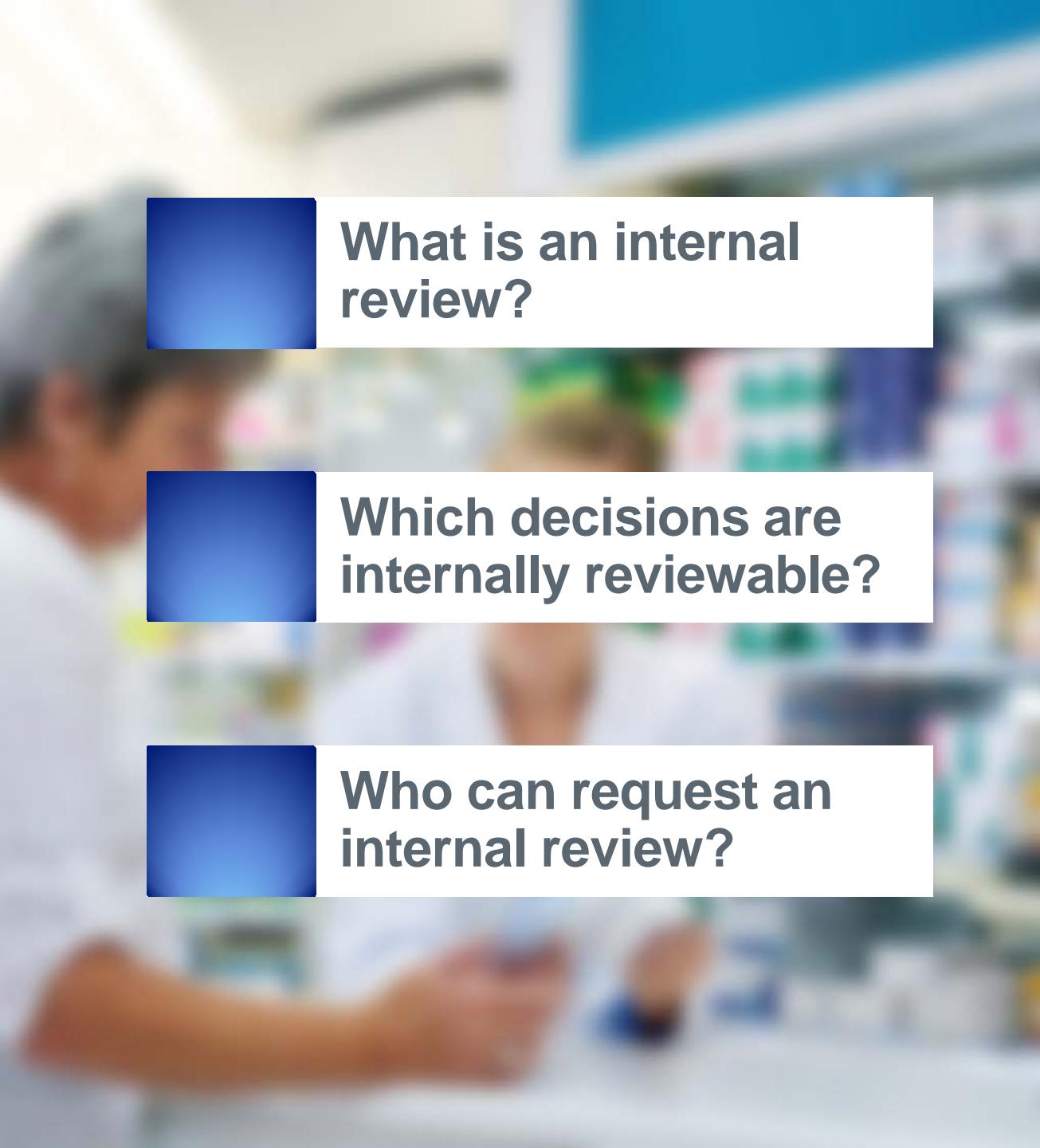
Internal review of TGA decisions

Legislative basis

Therapeutic Goods Act 1989 – section 60

Therapeutic Goods Regulations 1990 – regulation 48

Therapeutic Goods (Medical Devices) Regulations 2002 – regulation 10.7



What is an internal review?

Which decisions are internally reviewable?

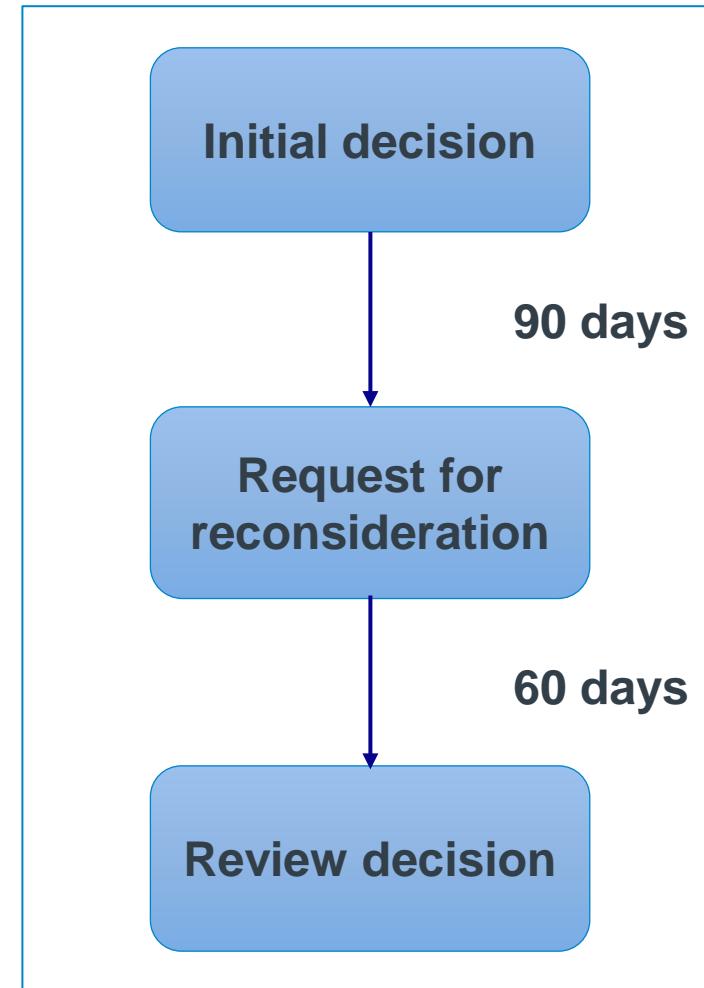
Who can request an internal review?

Internal review of TGA decisions

Further information in the TGA's [Guidance for requesting reconsideration of an initial decision \(Guidance\)](#)

Internal review process

- **Timing** is fixed & cannot be extended
- No prescribed form – TGA's Guidance sets out what email should include/attach
- Providing additional & 'new' information





Internal review process

People involved

- Review delegate
- Regulatory Decision Review Team
- Legal adviser
- Others (if required)



Initial decision statistics

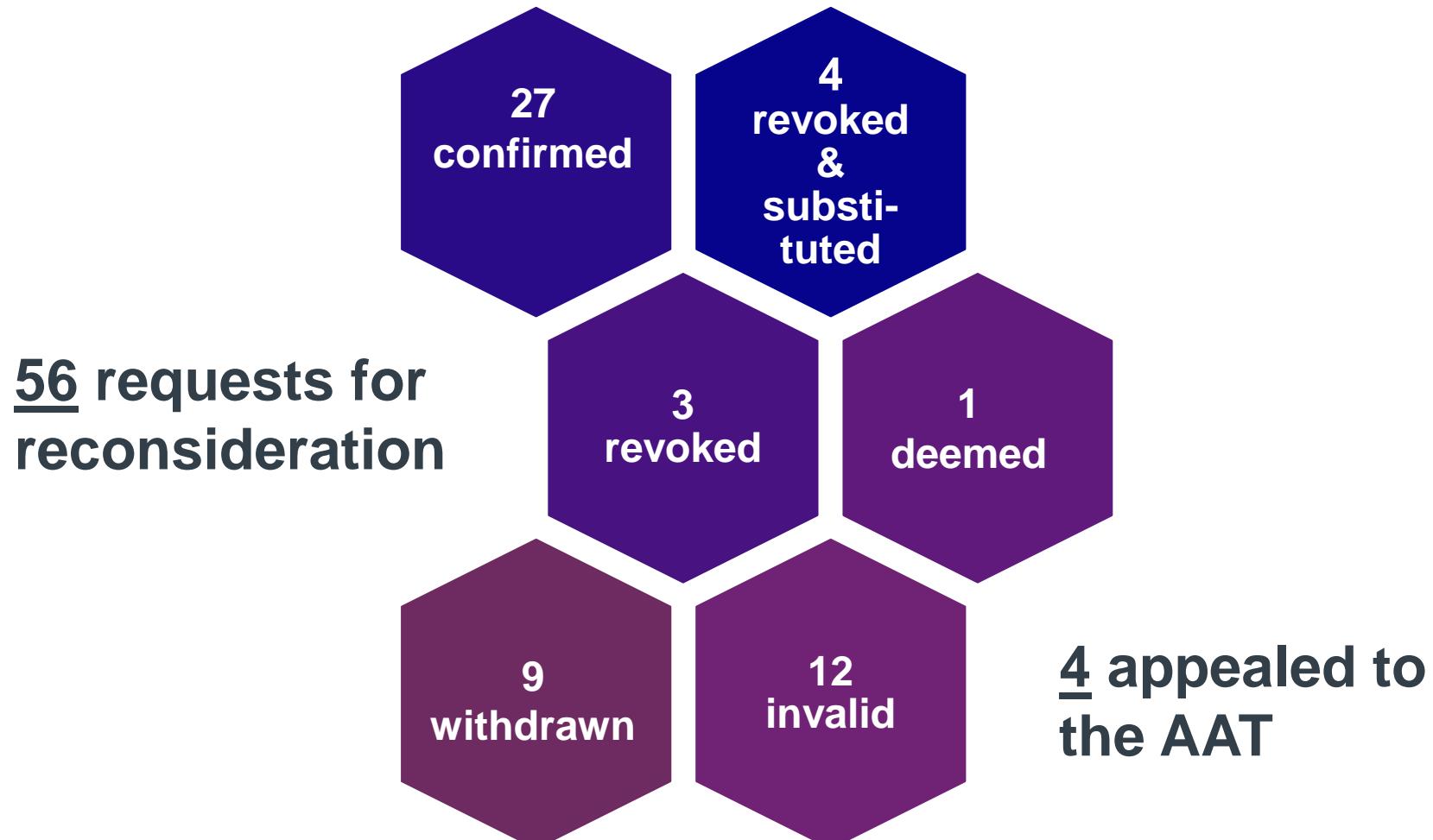
1 July 2020 – 30 June 2022

> 11,000 initial decisions relating to **prescription medicine** submissions alone

Source: [TGA Annual performance statistics report: July 2020 to June 2021](#) & [TGA Annual performance statistics report: July 2021 to June 2022](#)

Internal review statistics

1 July 2020 – 30 June 2022*



*Date request for reconsideration received

Making the process smoother....

Tips for requests for reconsideration

- Address the **merits** of the initial decision
- Submit **all information/documents** with the request
- Be **specific & explain how information/documents** address issues raised in the initial decision
- Consider outlining if there is any possible **compromise**

Making the process smoother....

Other things to keep in mind

- Timing, timing, timing!
- Role of decision maker vs role of applicant
- Seeking TGA guidance/input on what to include in a request for reconsideration

Website references

TGA website	www.tga.gov.au
TGA's Guidance for requesting reconsideration of an initial decision	https://www.tga.gov.au/resources/resource/guidance/guidance-requesting-reconsideration-initial-decision
TGA Annual performance statistics report: July 2020 to June 2021	https://www.tga.gov.au/about-tga/corporate-information/tga-plans-reports/annual-performance-statistics-reports
TGA Annual performance statistics report: July 2021 to June 2022	https://www.tga.gov.au/resources/publication/publications/regulator-performance-report-july-2021-june-2022

Therapeutic Goods Administration (TGA)

Exhibition booth No.1

Come chat with me today between 12.30 – 1:30pm





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