

Navigating Internal and External Reviews under the *Therapeutic Goods Act 1989*

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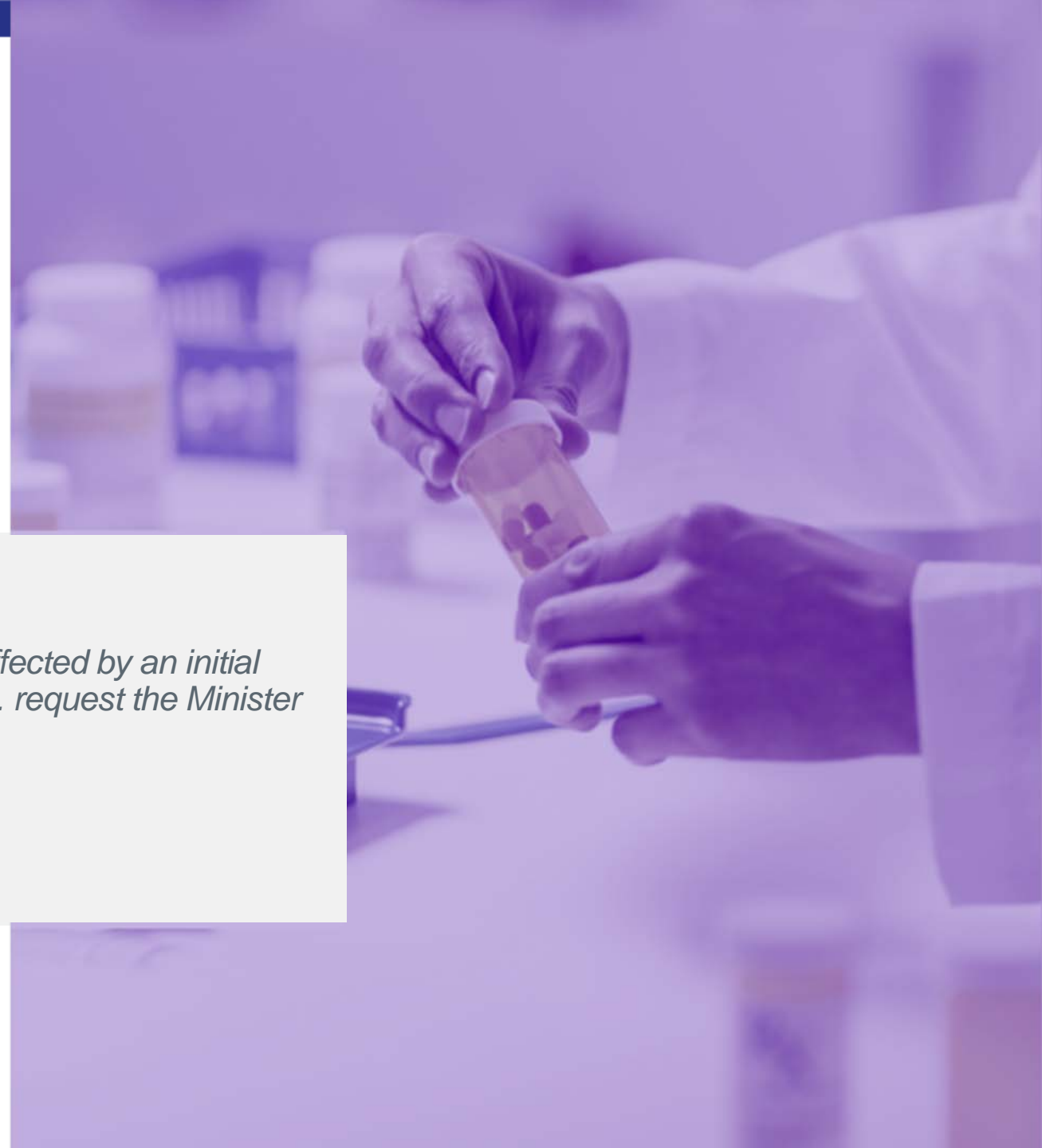
Therapeutic Goods Administration

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Reconsiderations

“Subject to this section, a person whose interests are affected by an initial decision may, by notice in writing given to the Minister... request the Minister to reconsider the decision.”

- Subsection 60(2), *Therapeutic Goods Act 1989* (Cth)



Requests for reconsideration

- Made under s 60 of the *Therapeutic Goods Act 1989* (Cth)
- Merits review – the task of the delegate is to consider the matter and come to the best decision on the material before them. Not a question of finding error in the first instance decision
- Available with respect to an ‘initial decision’ of the Secretary, as defined under s 60(1)
 - Not available for some decisions: preliminary assessment, s 31 notices etc (ss 60(1AA), (1A))
- May only be made by a ‘*person whose interests are affected by*’ the initial decision (‘Standing’)
 - *Becton Dickinson Pty Ltd and Minister for Health and Aged Care* [2025] ARTA 16
- 90 days to make the request – strict deadline
- Limitations on taking into account information received from the person requesting reconsideration after the request is made
- 60 day timeframe, after which a deemed confirmation of the initial decision
- Decision of the Minister or delegate reviewable by the Administrative Review Tribunal



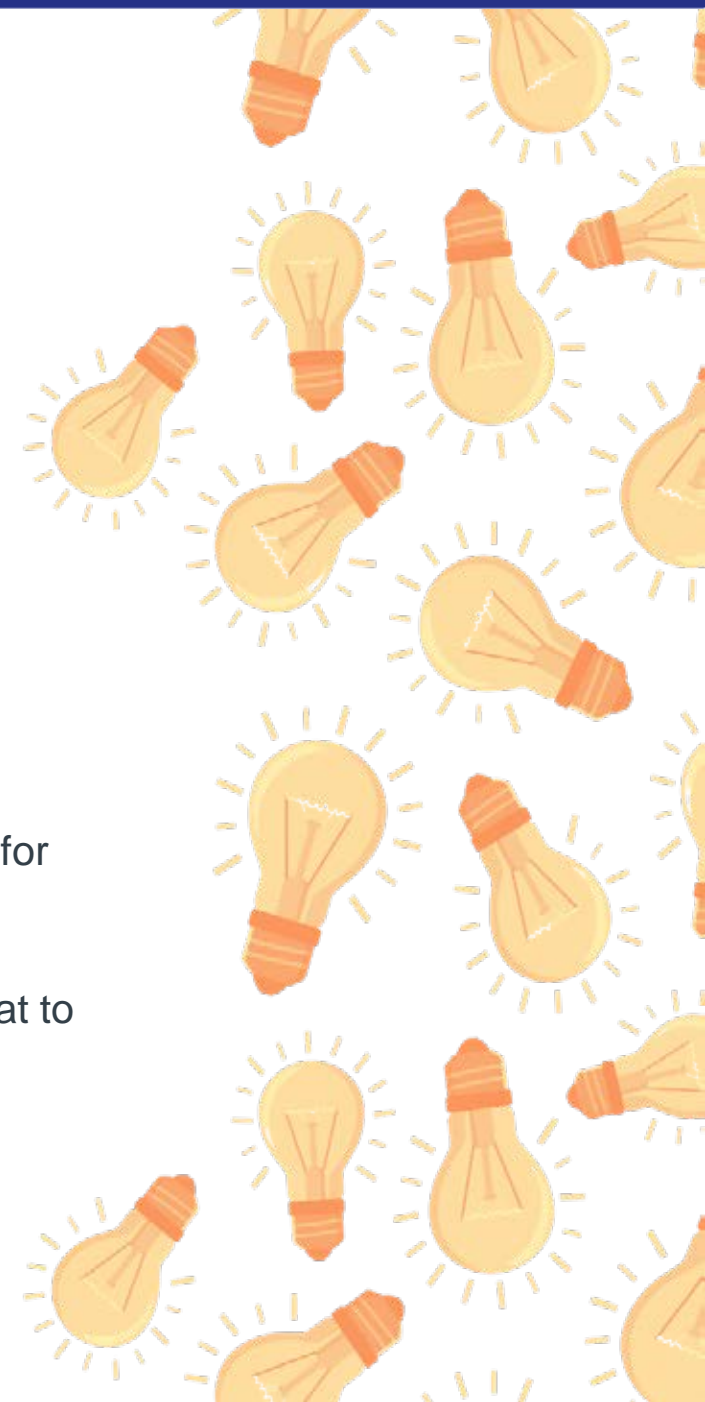
Requests for reconsideration – Practical tips

- It is **merits review**, not judicial review
 - Focus on the data and the legislative test the delegate needs to establish to achieve the outcome you're seeking
 - Play the ball, not the people
 - Complaints about process not especially relevant
- Be civil, even if you disagree with or are frustrated by the first instance decision
- Take the concerns of the first instance delegate seriously
- Make sure you get everything in with the request – don't assume you'll get another chance
 - Ideally, get material in *before* the request, in the initial application process
 - Providing material that was available to you, but not provided to the TGA in the initial application process for a prescription medicine, can sometimes result in remittal to a delegate of the Secretary (s 60A)
 - Failure to provide material may limit options in, or result in remittal by, the Tribunal as well (s 60A)



Requests for reconsideration – Practical tips

- Help the delegate get to the outcome (and do so within the 60 days!):
 - Put arguments clearly and concisely
 - Tell the delegate where to find the evidence you rely on
 - Cite the evidence which substantiates statements of opinion
 - Engage with any contrary evidence
 - Tie your argument back to what the Act requires
- Be constructive:
 - If you would like the delegate to consider alternatives, make a concrete proposal (for example, exact wording of a revised indication, alternative draft PI, new risk management plan etc.)
 - If the delegate requests further information or submissions on a point, try to get that to them ASAP – there are no stop clocks on reconsideration

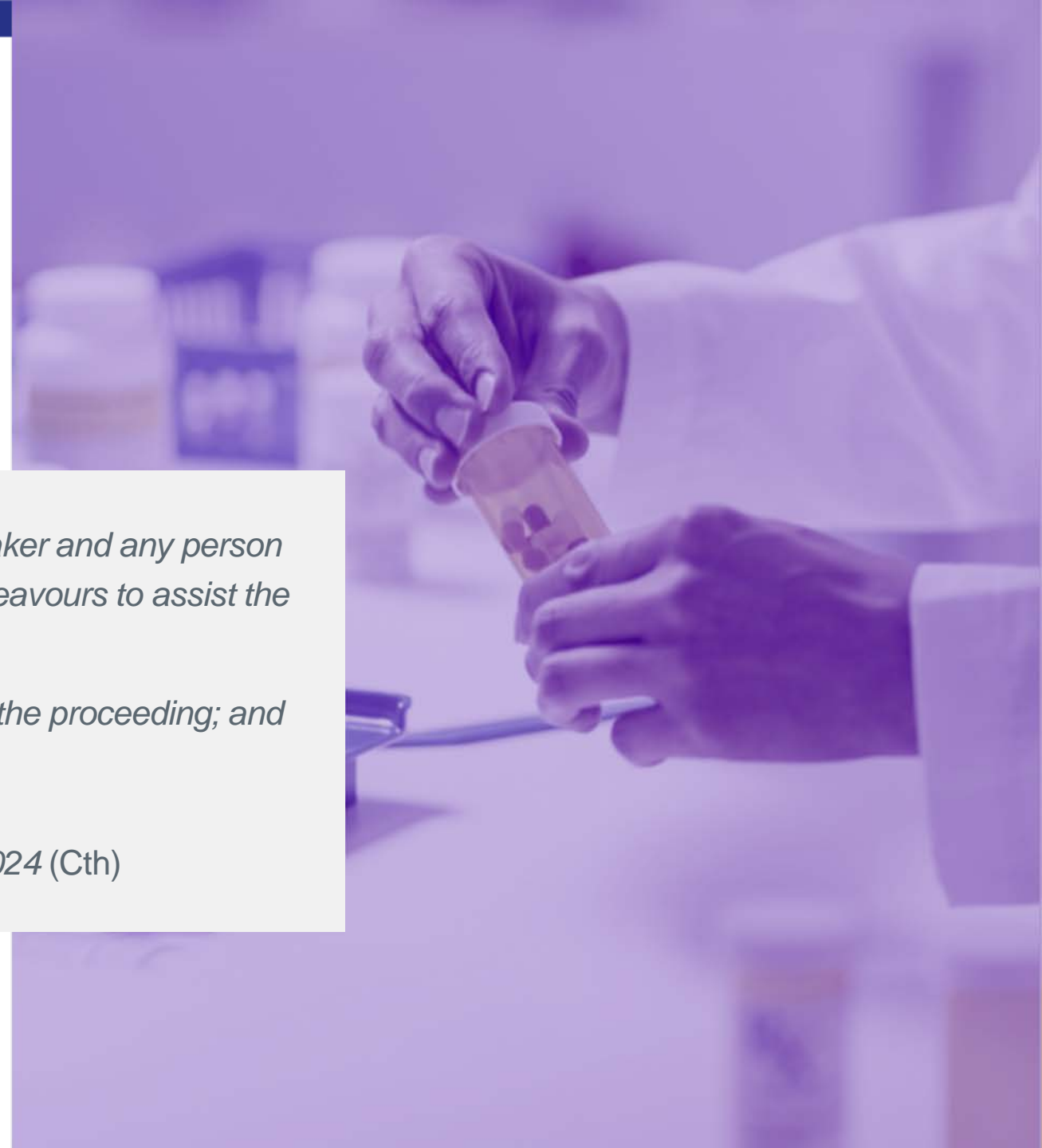


Administrative Review Tribunal

“In a proceeding for review of a decision, the decision-maker and any person representing the decision-maker must use their best endeavours to assist the Tribunal to:

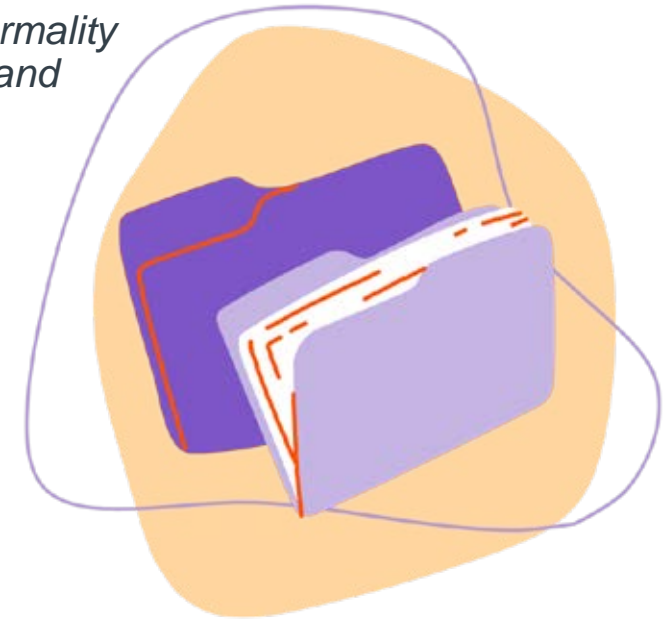
- (a) make the correct or preferable decision in relation to the proceeding; and*
- (b) achieve the objective in section 9.”*

- Subsection 56(1), Administrative Review Tribunal Act 2024 (Cth)



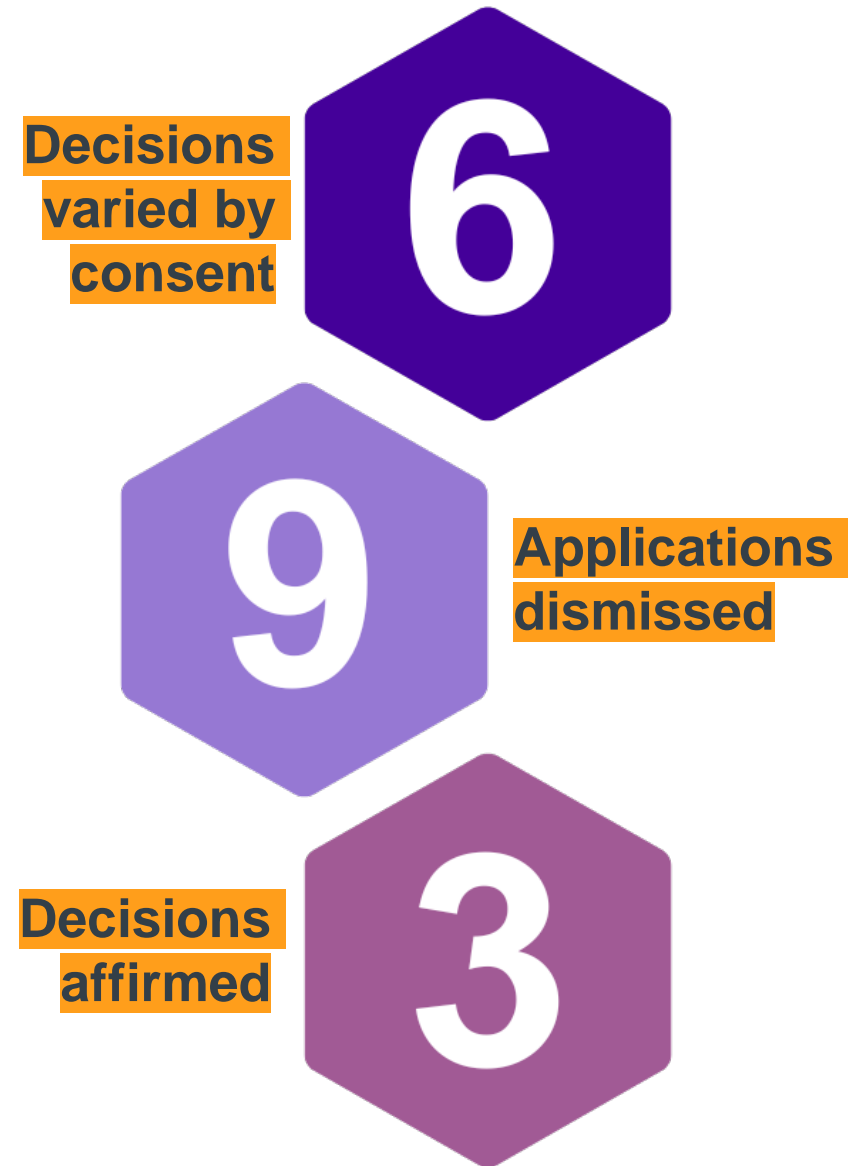
The Administrative Review Tribunal

- Replaced the Administrative Appeals Tribunal on 14 October 2024 – processes, procedures etc. remain similar
- Again, a merits review process – not seeking to demonstrate error, instead focused on getting to the right decision
- Strictly speaking, not an adversarial process - our role is to assist the Tribunal to make the correct or preferable decision
- Both parties are required under s 56 to use best endeavours to assist the Tribunal in achieving its objective under s 9, being to provide '*an independent mechanism of review that:*
 - (a) *is fair and just; and*
 - (b) *ensures that applications to the Tribunal are resolved as quickly, and with as little formality and expense, as a proper consideration of the matters before the Tribunal permits; and*
 - (c) *is accessible and responsive to the diverse needs of parties to proceedings; and*
 - (d) *improves the transparency and quality of government decision-making; and*
 - (e) *promotes public trust and confidence in the Tribunal.'*
- Decisions are usually public
- Can be resolved by consent if the parties agree
- Appeals on matters of law to the Federal Court of Australia



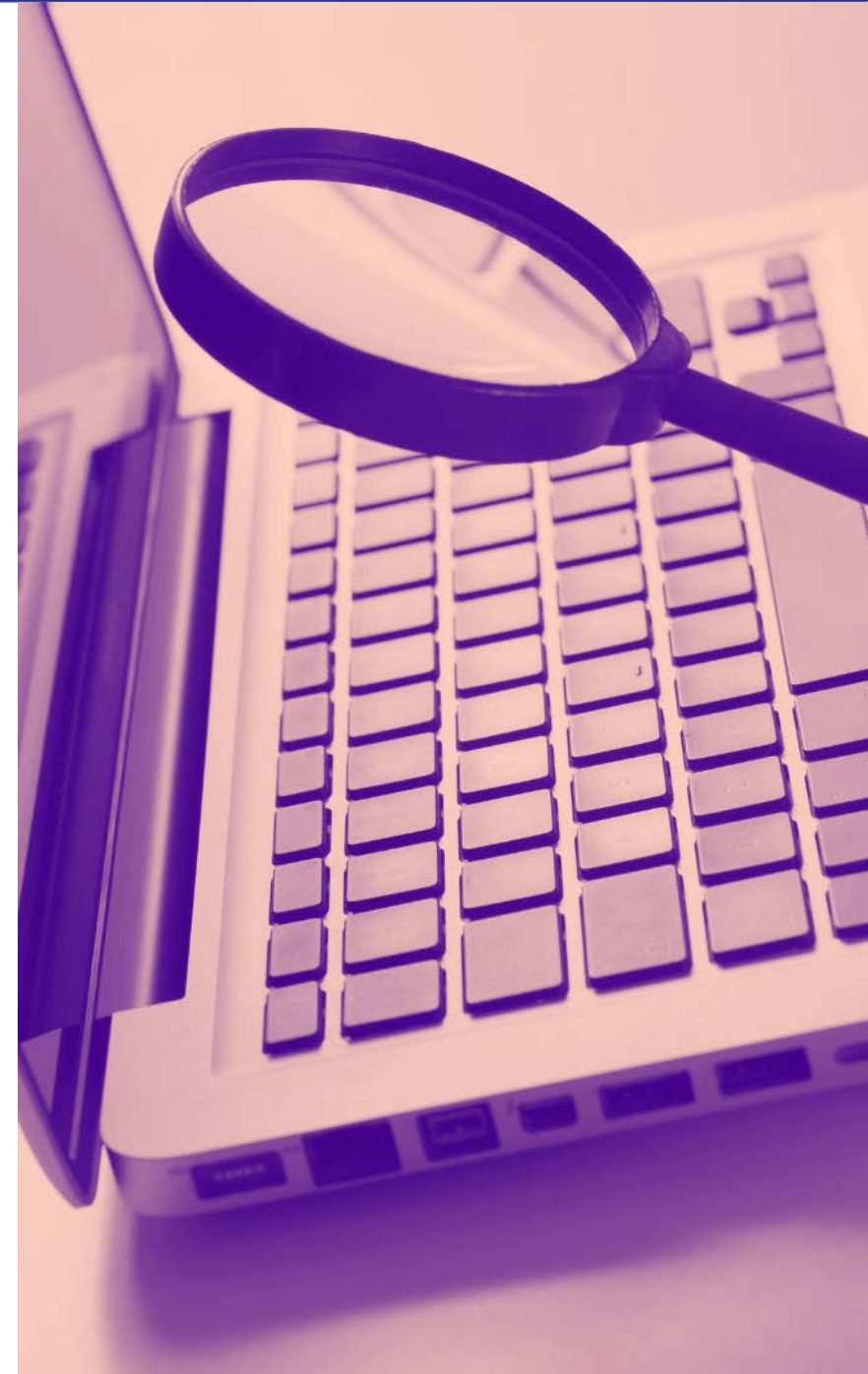
Summary - Outcomes of AAT/ART cases

- Outcomes from January 2020 to date in TGA + ODC decisions (incl. FOI) before the AAT or ART
- Most matters resolve before final hearing
- Dismissal includes Applicant withdrawal, dismissal on jurisdictional or standing grounds
- No decisions set aside by the Tribunal without the Respondent's consent in that time



ART review of TG Act decisions

- Role of our team is to help the Tribunal reach the correct or preferable decision
- Matters can go on for a long time (>2 years is not uncommon)
- Focus is on expert evidence, not decisions of delegates, evaluation reports etc. at first instance or reconsideration
- In some matters (primarily decisions on registration applications), need to be mindful of s 60A
- Can (and often do) resolve matters by consent
 - Proposed compromises from applicant (narrowed indication etc.)
 - New evidence (usually data, rather than opinion)
 - Often will have conciliation or settlement conference after the evidence is filed
- If a case goes to hearing, can be long and expensive



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Exhibition booth No.60

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