Priority Designation Workshop

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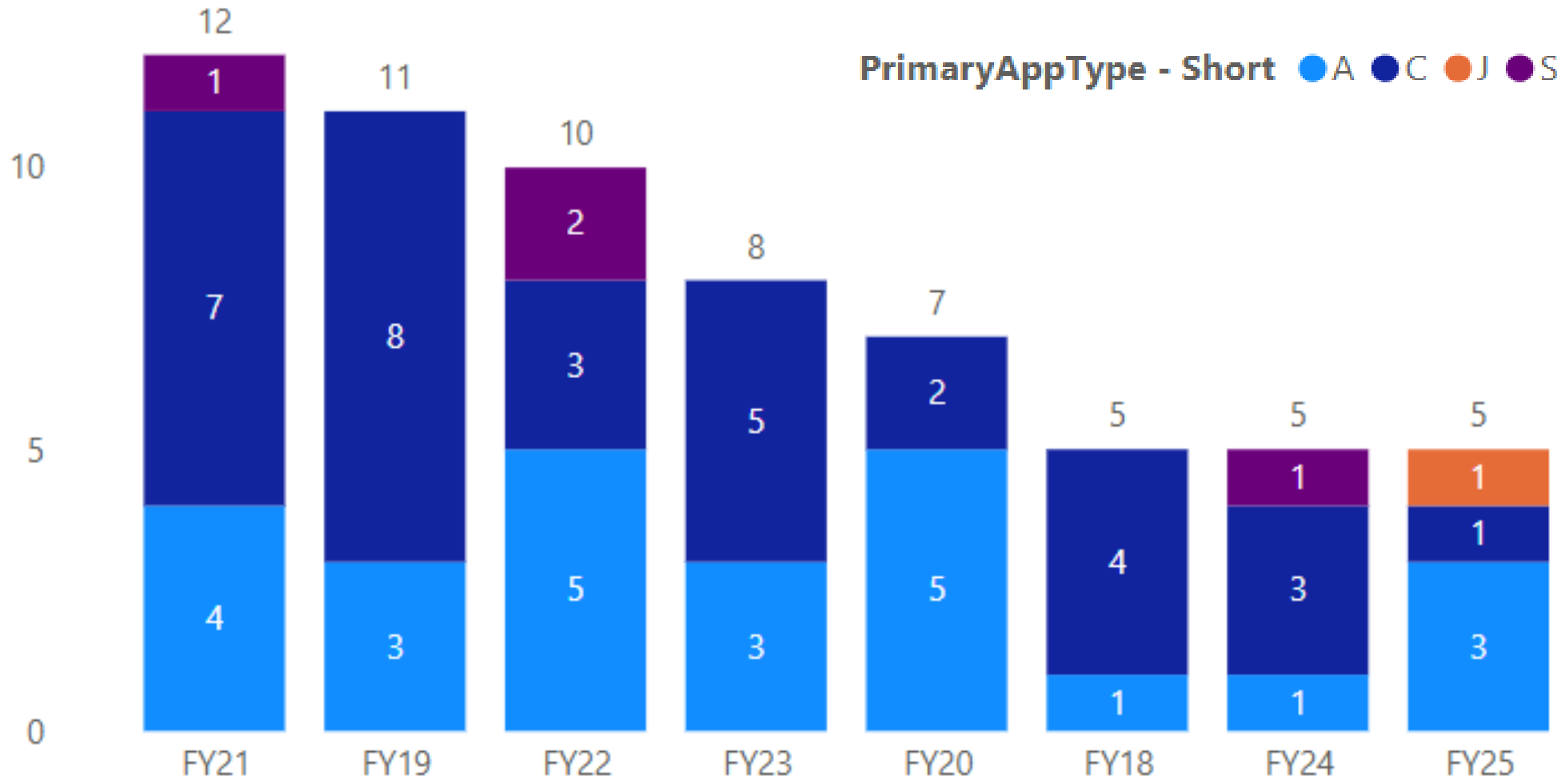
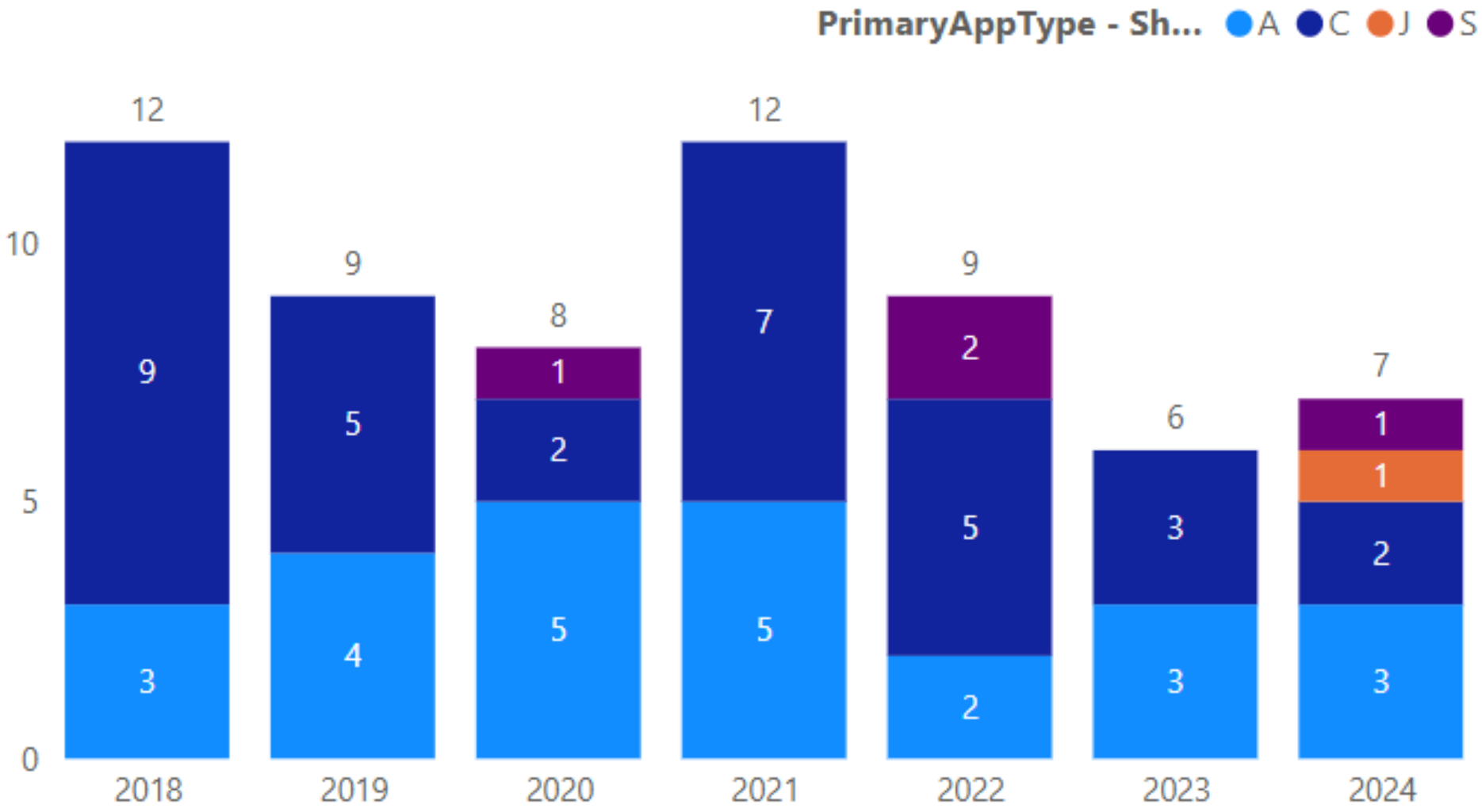
Objectives of the workshop

- Improve your understanding of the priority designation process
- Discuss practical tips and best practices to satisfy eligibility criteria

Priority submissions by financial year and type



Priority submissions by calendar year and type



Overview of the priority registration process

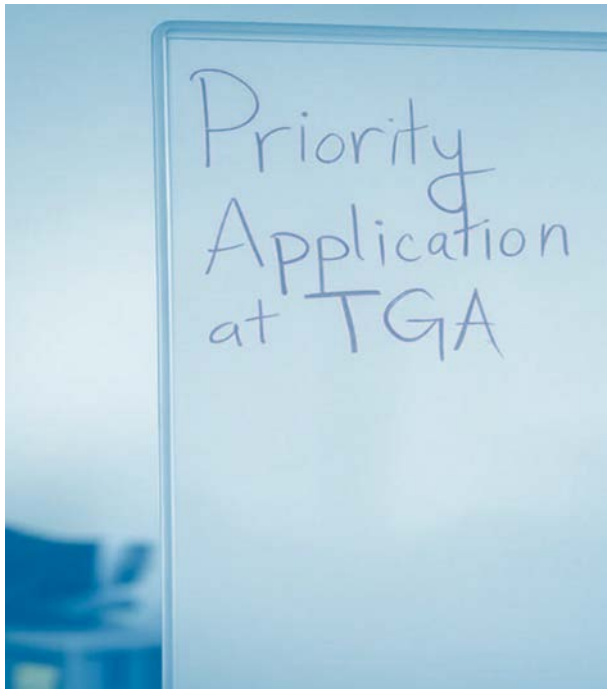
Definition and Importance

- Expedited registration for eligible medicines
- Reduced timeframe from 255 to …. working days

Overview of the priority registration process

Definition and Importance

- Expedited registration for eligible medicines
- Reduced timeframe from 255 to 150 working days



Legislation

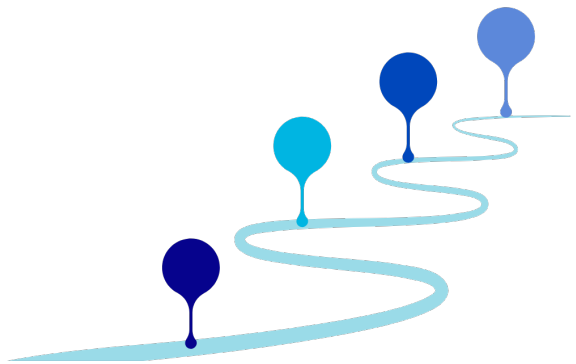
- Therapeutic Goods Regulations 1990
- Therapeutic Goods Act 1989

Priority determination process

- Allows TGA to decide if a medicine is eligible for the priority review pathway.
- Recommended three months before the planned registration submission date.

Steps in the Determination Process

1. Early Notification: Notify TGA at least one month prior to lodgement.
2. Access to TGA Business Services (TBS): Obtain a TGA Client ID and access to the TBS portal.
3. Submitting the Application: Use the designation/determination application e-form and pay the priority determination fee.
4. TGA Assessment: TGA assesses the application within 20 working days.
5. Notification of Decision: Sponsors are notified of the decision via email.



Eligibility criteria overview

1. New Medicine: The medicine is a new prescription medicine or a new indications medicine.
2. Serious Condition: The indication is for the treatment, prevention, or diagnosis of a life-threatening or seriously debilitating condition.
3. Comparison Against Registered Therapeutic Goods:
   - No therapeutic goods are registered for the condition, or
   - The medicine provides a significant improvement in efficacy or safety over existing registered goods.
4. Major Therapeutic Advance: The medicine provides a major therapeutic advance.

Addressing the criteria

Criteria 3 - Justification of significant improvement in safety or efficacy

- Improved efficacy for the entire population relevant to the therapeutic indication
- Better safety profile for the entire population relevant to the therapeutic indication.

Addressing the Criteria

Criteria 3 - Justification of significant improvement in safety or efficacy

- Supporting evidence should be based on clinical trial data.
- Increased safety or efficacy should be demonstrated through established safety and efficacy endpoints that demonstrate direct clinical benefit.

Addressing the criteria

Criteria 3 - Justification of significant improvement in safety or efficacy

- Comparator studies are expected to be generated (pivotal study reports). However, scientific argument/justification for the significant improvement in safety or efficacy of the medicine relative to products not studied in available clinical trials (this may involve cross study comparisons) may be considered.

Addressing the criteria

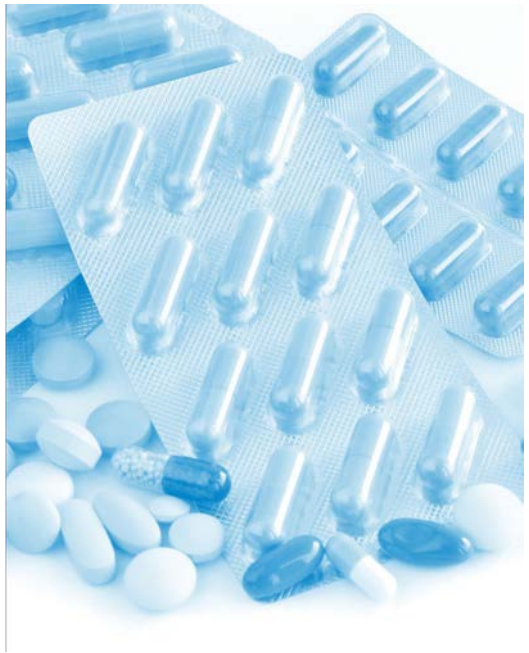
Criteria 3 - Justification of significant improvement in safety or efficacy

- The TGA will not assess significant benefit against comparators that are a subject of concurrent determination or registration applications, those that are the subject of a provisional registration submission that is under review by TGA, or medicines that are currently provisionally registered

Addressing the criteria

Criteria 4 - Justification of major therapeutic advance

- The magnitude of the demonstrated improvement in safety and/or efficacy
- Endpoints that directly demonstrate clinical benefit
- The impact on patient outcomes taking into account both safety and efficacy



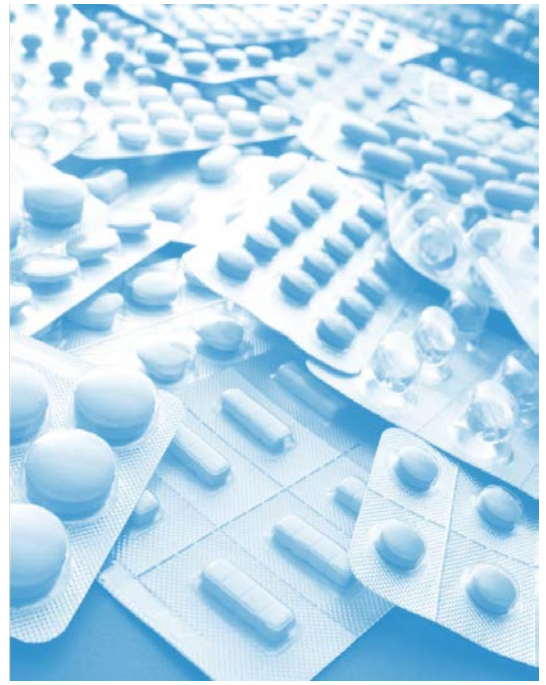
Addressing the criteria

Criteria 4 - Justification of major therapeutic advance

- The magnitude of the advance in relation to other therapeutic goods registered for the indicated population.
- Where no product is on the ARTG, the comparison should occur against the standard of care
- The strength of evidence (general TGA adopted guidelines about appropriate trial design apply).

Summary

- Criterion 3: "Is the new medicine better than what's currently available?"
- Criterion 4: "Is the new medicine a major breakthrough in treatment?"



Questions?

Scan the QR code with your device to submit a question.