Prostheses List
purpose, definitions and scope

WELCOME

Webinar- 8 September 2021

Webinar Structure

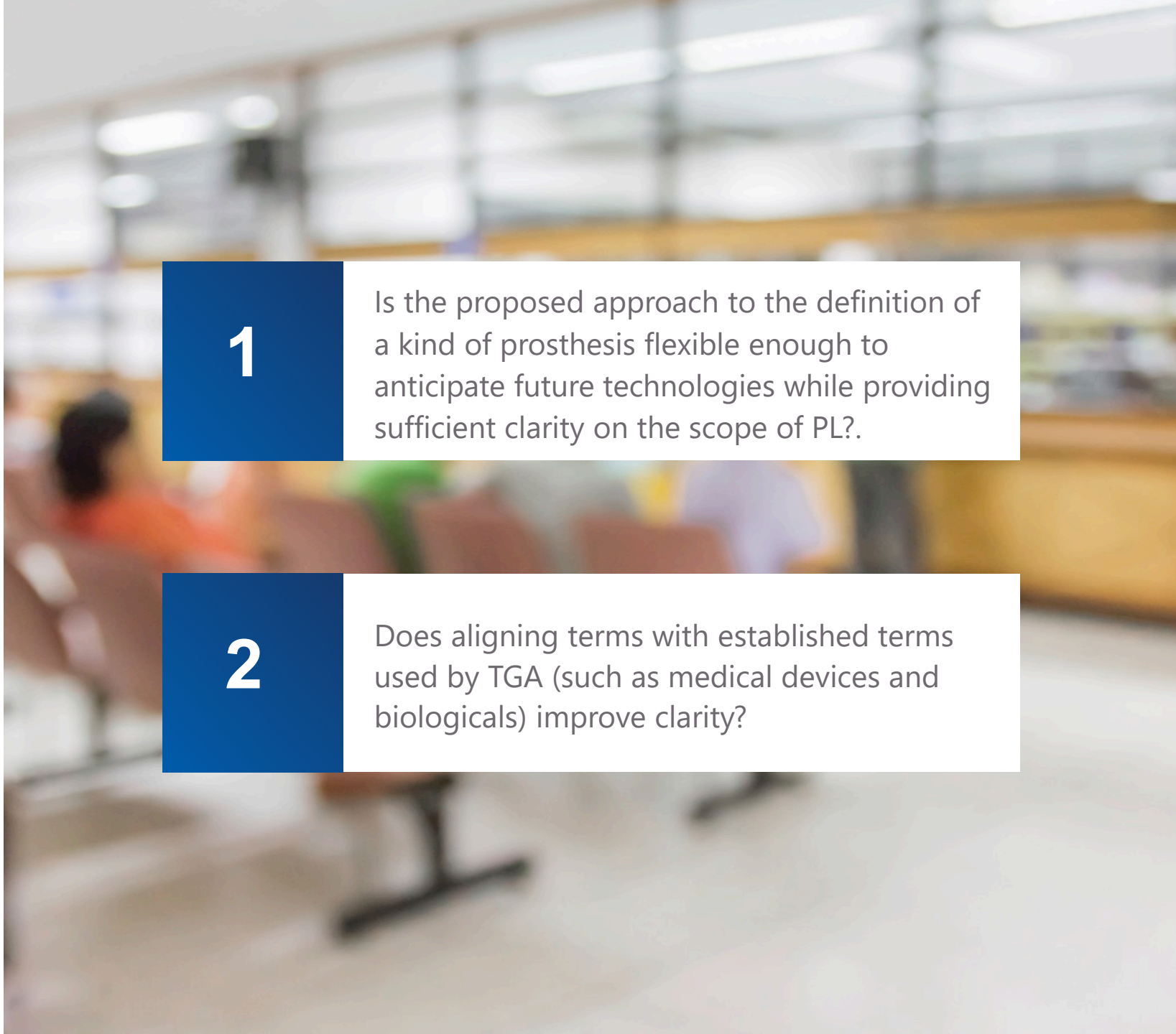
- **Content Blocks:** Existing arrangements – proposed arrangements and pre-submitted questions
    1. Definition and Scope
    2. Listing Criteria
    3. Name
    4. Consequences of Changes
- **Audience Polling:** in each segment
- **Live Q&A:** Last section *Vote please*

Context

- The webinar discussion assumes that participants understand the background of the PL reforms
- Information on this background can be obtained from the Department website or by contacting us on prosthesesreform@health.gov.au
- PL first established in 1985 to set a benefit amount that Private Health Insurers will pay Hospitals for listed prostheses used on a private patient with an appropriate insurance cover as part of their in-hospital treatment.
- Since inception it has been reviewed a number of times, with each review finding some room for improvement
- Modernising and Improving the private health insurance Prostheses List – Budget announcement
- The Australian Government is investing $22 million over 4 years
- Prostheses List Reform Taskforce established 1 July 2021
- Reduce the cost of medical devices used in the private health sector and streamline access to new medical devices, which will improve the affordability and value of private health insurance for Australians.
- To better align the price set for medical devices on the PL for private providers with those paid for in competitive markets such as those in the public hospital system.

Discussion topics for content section # 1

Definition & Scope



1. Is the proposed approach to the definition of a kind of prosthesis flexible enough to anticipate future technologies while providing sufficient clarity on the scope of PL?.

2. Does aligning terms with established terms used by TGA (such as medical devices and biologicals) improve clarity?

Definition & Scope

Existing Arrangements

- The PHI Act requires private health insurers to pay prices listed in the PL to:
  - patients with appropriate private health insurance cover
  - for approved kinds of prostheses received as part of the hospital or hospital-substitute treatment
  - for which a Medicare benefit is payable.

- Currently, a prosthesis is not explicitly defined but is taken as a product of a kind listed in the Schedule of the Prostheses Rules (the PL).

- PL terminology is not aligned with other relevant legislation, especially therapeutic goods legislation.

Definition & Scope

Proposed Amendments

- **The focus is on the device being one that is intended to remedy a medical condition,** where the intention of the accompanying medical procedure is to remedy disease or dysfunction through use of the specific medical device. The device should not be one that is used as an adjunct to the procedure (e.g. sutures, haemostatic agents, adhesives).
- **include in the PHI legislation a definition of a kind of prosthesis**:
  - A medical device or human tissues item (biological) intended to be used for therapy and that meets the criteria for listing as set up in the Prostheses Rules is declared to be a kind of prosthesis for the purposes of the PHI Act if it is listed in the PL
  - Therapy includes monitoring, treatment or alleviation of disease or compensation for an injury or disability.
- **Alignment with the TGA terminology**: It is proposed to align the meanings as far as possible of a medical device, biological, accessory, implantable medical device, short-term or long-term, surgically invasive medical device, device for therapy, etc

Poll Question

Should the terminology used in the Prostheses List be aligned to the terminology used in the TGA?

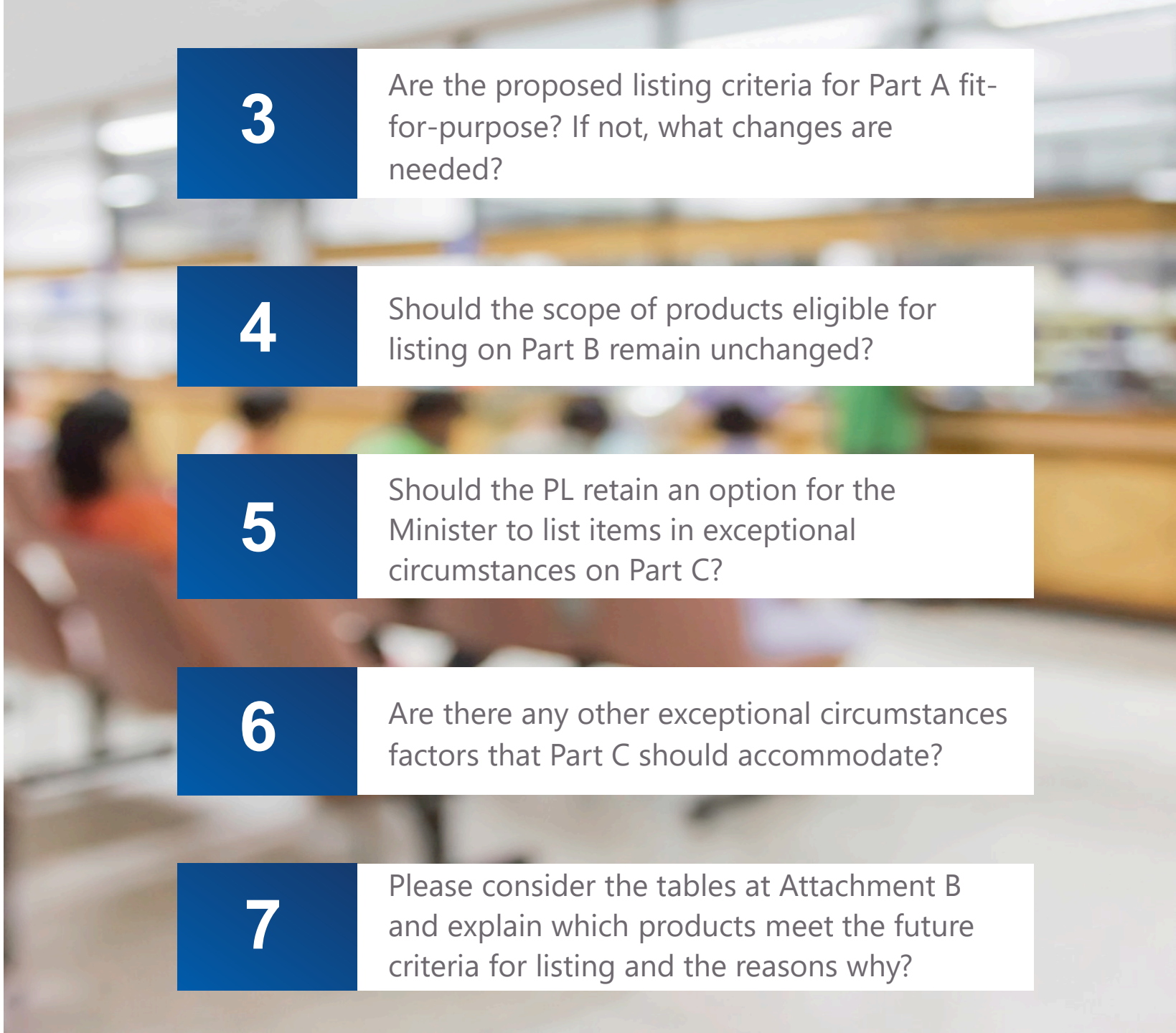
Clarification: paper refers to same words (terminology). Not the same process for inclusion/exclusion of items.

[] Yes [] No

The live panel addresses participant's pre-uploaded questions

Discussion topics for content section # 2

Listing Criteria



3	Are the proposed listing criteria for Part A fit-for-purpose? If not, what changes are needed?
4	Should the scope of products eligible for listing on Part B remain unchanged?
5	Should the PL retain an option for the Minister to list items in exceptional circumstances on Part C?
6	Are there any other exceptional circumstances factors that Part C should accommodate?
7	Please consider the tables at Attachment B and explain which products meet the future criteria for listing and the reasons why?

Listing Criteria

Existing Arrangements

- The PHI Act sets out the following requirements when a price is payable with respect to prostheses. In line with this, private health insurers are required to pay a price for a product if:
  - The product is listed on the PL.
  - The patient receives the product as part of hospital treatment or hospital substitute treatment.
  - The patient has appropriate health insurance to cover for the treatment.
  - A Medicare benefit is payable for a service associated with the use of the product.
- Prostheses are a subset of medical devices, and human tissues items.
- Products listed in any part of the PL are expected to be used for therapy (treatment or alleviation of disease or compensation for an injury or disability), not for diagnosis, prediction, or prognosis.

Listing Criteria

Existing Arrangements

- **Specific requirement for Part A:**
  - Products expected to be medical devices
  - Product must be entered on the Australian Register of Therapeutic Goods (ARTG).
  - Products should be surgically implanted or be essential and specifically designed as a single-use aid for implanting a prosthesis, or be critical for maintaining ongoing-function of the surgically implanted prosthesis.
  - Products should be at least of similar clinical effectiveness and cost effectiveness compared to alternative products on the PL or alternative treatments.
- **Specific requirement for Part B:**
  - Products eligible for listing on Part B are human tissue items used for replacement of anatomical parts. There will be a separate consultation paper for Part B.
- **Specific requirement for Part C:**
  - Products expected to be medical devices
  - Devices approved by the Minister for listing.
  - Assessed by the Medical Services Advisory Committee (MSAC) as clinically effective and cost effective.
  - satisfy an unmet clinical need

Listing Criteria

Proposed Amendments

- Many of the existing arrangements are expected to continue:
  - Private health insurance cover for approved kinds of prostheses, hospital treatment, and availability of the Medicare services (PHI Act)
  - The expectation that devices or human tissues are used for therapy, not diagnosis.
  - The requirement for the inclusion of a medical device or biological in the ARTG.

- ARTG entry criterion to be clarified:
  - information on the ARTG is to be consistent with information on the PL. This will clarify that the price is payable for the prosthesis as authorised for supply by the TGA.

Listing Criteria

Proposed Amendments

Specific to Part A:

- The existing requirements will continue to apply but it is proposed that both the implantable medical devices and single-use short-term or long-term surgically invasive medical devices for a specified therapy will meet the listing criteria.
- Devices that are essential and specifically designed as a single-use aid for implanting a prosthesis, or are critical for maintaining ongoing-function of the surgically implanted prosthesis will also continue be eligible for listing on the PL.

  With some exceptions:

  × Devices intended for general purpose (e.g. sutures, surgical staples, haemostatic agents)

  × Consumables (e.g. needles, tubing, topical adhesives, and sealants)

  × Accessories. Devices designed and intended by the manufacturer to always be used together will no longer be separately funded through the PL.

Listing Criteria

Proposed Amendments

Specific to Part B:

- It is anticipated that Part B will continue to cover human tissue products that are substantially derived from human tissue where the tissue has been subject to processing or treatments, and whose supply is governed by state or territory law.
- The implanting by surgical intervention criteria will remain and will be prescribed in the Prostheses Rules.
- A separate discussion paper will explore the Part B issues that are proposed for amendment

Specific to Part C:

- It is proposed that Part C will continue, with the criteria for listing covering high cost and high clinical value devices that demonstrate:
- high and unmet clinical need and
- clinical and cost-effectiveness assessed by the MSAC and
- demonstrated cost saving to the health system in comparison to current treatments.

Poll Questions

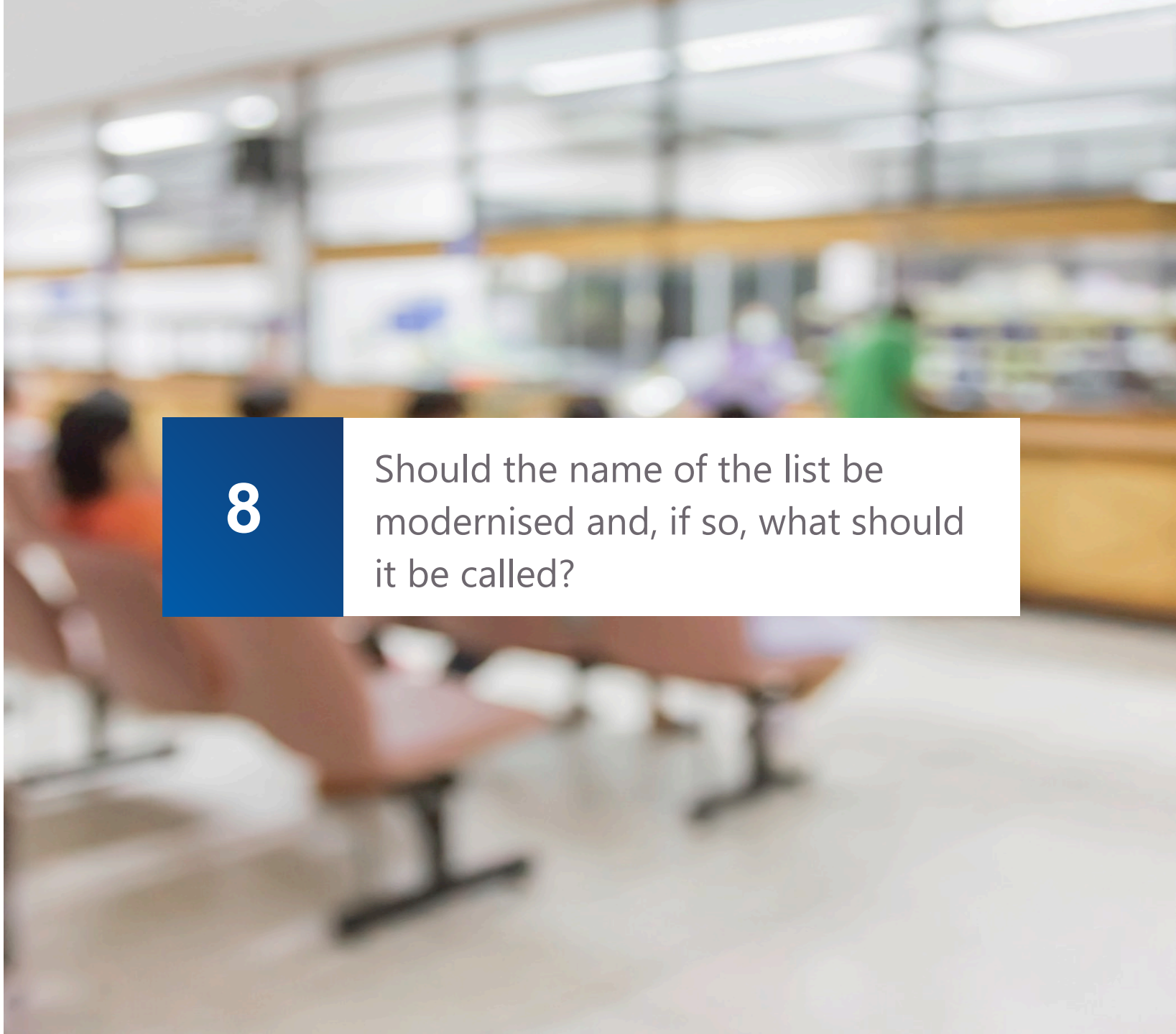
- **Are the proposed listing criteria for Part-A fit-for-purpose?**
  [] Yes [] No

- **Should the PL retain an option for the Minister to list items in exceptional circumstances on Part-C?**
  [] Yes [] No

The live panel addresses participant's pre-uploaded questions

Discussion topic for content section # 3

Name



8 Should the name of the list be modernised and, if so, what should it be called?

Name

Existing Arrangements

- In common English, many people understand a prosthesis as being prosthetic limbs, but these products are excluded from being eligible for listing on PL.

Proposed Amendments

- Adopt a name that will clearly differentiate prosthetic limbs from the kind of medical replacement items on the list.
- More accurately describe the group of items covered

Poll Questions

- **Should the Prostheses List adopt a name that will clearly differentiate the items listed from prosthetic limbs?**
  [] Yes [] No

- **If the name of the list were to change, which of the following words would you identify with the kind of items that will be on the list?**

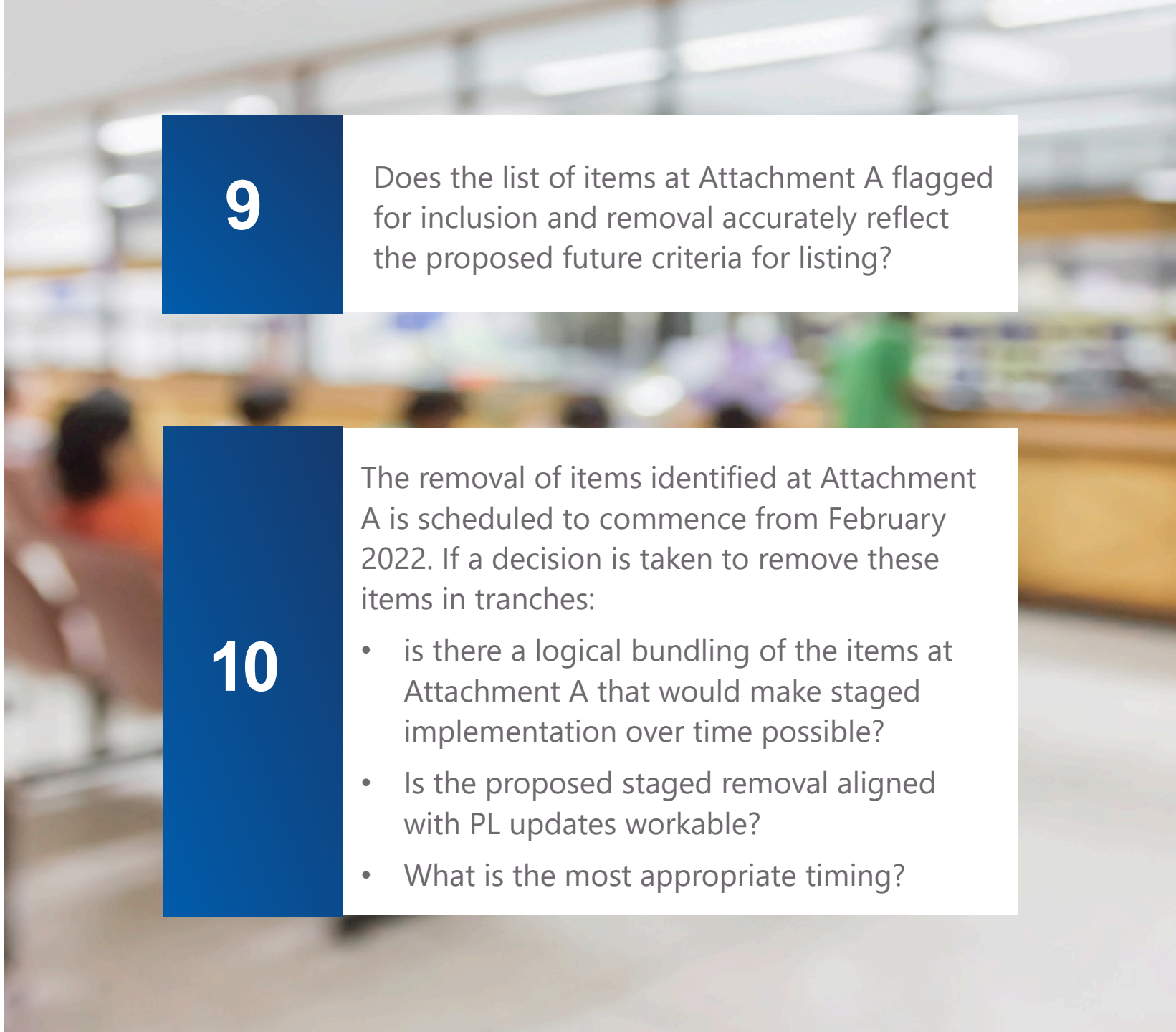
  [] Therapeutic Goods list
  [] Therapeutic devices list
  [] Medical & Biological devices list
  [] Medical technology list
  [] Other

The live panel addresses

No questions received

Discussion topics for content section # 4

Consequences of Changes



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Does the list of items at Attachment A flagged for inclusion and removal accurately reflect the proposed future criteria for listing?

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The removal of items identified at Attachment A is scheduled to commence from February 2022. If a decision is taken to remove these items in tranches:

- is there a logical bundling of the items at Attachment A that would make staged implementation over time possible?
- Is the proposed staged removal aligned with PL updates workable?
- What is the most appropriate timing?

Consequences of Changes

- General Miscellaneous Category
- Implementation of Prostheses List Improvements Scheduled to start in February 2022 with the removal of ineligible items from the General Miscellaneous Category
- Timing of changes
- Bundling of items
- Linking to regular PL updates

Poll Questions

Based on the proposed criteria for listing and the items listed on Attachment A

Does the list of items flag for inclusion and removal meet the new criteria for listing?

[] Yes [] No

The first bundle of items to be removed from the list is scheduled for February 2022

Is the proposed staged removal aligned with PL updates workable?

[] Yes [] No

The live panel addresses participant's pre-uploaded questions

Live Q & A

Have you voted for the questions we have not addressed yet?

Prostheses List Reform Taskforce

Thank you

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