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Prostheses List Reform Taskforce
Office of Health Technology Assessment
Technology Assessment and Access Division
Australian Government Department of Health

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Dear Taskforce Members,

Re: Feedback in relation to *Prostheses List Reforms Consultation Paper No 1: Prostheses List – Purpose, Definitions, and Scope*

RACS is the leading advocate for surgical standards, professionalism and surgical education in Australia and New Zealand. Our Fellows are among the primary users of prostheses in the Australian healthcare system.

Our Fellows' focus is on ensuring that their patients have the best possible outcomes, and this is only achievable if patients have access to the medical devices best suited to their particular clinical circumstances.

RACS is supportive of reforms to the Prostheses List (PL) which reduce costs to insurers as long as clinicians (in consultation with patients) continue to have access to the most appropriate medical devices in order to deliver the best long-term patient outcomes.

RACS wishes to register our concern about the potential consequences of the removal of general use products which have mainly been listed in part A of the PL, such as sutures, surgical staples, sealants for wound dressings, and other consumables. RACS is concerned that the changes may result in reduced clinical product choice, and ultimately reduced patient outcomes.

RACS notes that the Government has an expectation that for those items removed insurers and private hospitals will reach an agreement on a market based alternative funding arrangement and one that does not involve out of pocket costs for the consumer.

However, RACS is concerned that an alternative funding arrangement may result in differences in funding as a result of significant variability in private hospital size, market share and negotiating power with the various PHI funds. The changes may result in less choice of products / devices in certain hospital settings, and clinicians placed under pressure to use "whatever is available", which could well be lowest cost products, rather than clinicians' preferred products which would be chosen to achieve best patient outcomes.

In particular, RACS is concerned that where appropriate funding arrangements are not in place clinicians may be put in the position where they must advocate to patients for the use of products which will result in a significant out of pocket cost, instead of a product they believe is inferior, but which is fully funded. It is possible that the private hospital provider may not even give clinicians the choice, and unilaterally make a decision to only stock a product of their choice with the determination based on price rather than in consultation with clinicians regarding needs.

These concerns reflect those expressed by stakeholders at earlier stages of this reform process, including concerns outlined in the EY report, 'Review of

the General Miscellaneous Category of the Prostheses List' 31 July 2020, that unintended consequences of the removal of products from the PL may include:

• Patients left out of pocket
• Diminished access to devices
• Lack of choice of specific device required for specific procedures
• Cost burden on hospitals
• Patients forced into the public system
• Administrative upheaval

In addition to raising our concerns regarding the proposed removal of certain items RACS would like to raise our concerns with the fact there appears to be no scope for inserting a device for prevention of a condition. The definition for an item to be on the PL list is therapeutic intervention, including; monitoring, treatment or alleviation of disease or compensation for an injury or disability. To illustrate; urologists insert a hernial mesh into the external internal ring as part of the penile implant procedure to prevent herniation. It seems as though this mesh now may not be covered.

In light of these concerns RACS believes it is worth considering a 'consumable' section to the PL to ensure that all such items remain fully available to clinicians and their patients in all settings.

Should the Government decide to remove the items as currently described RACS believes the planned 'removal date' of February 2022 is too soon. Any alternative funding arrangements will need to be sorted out and finalised, having had the input of clinicians, before the items are removed. The current considerable demands on the hospital system mean that it may be difficult to delegate the time and resources required to negotiate appropriate contracts with PHI, and to seek clinical input. Implementation over an 18-month to two-year period would be more feasible.

If implementation of the changes occurs RACS believes it would be appropriate for access to, and use of, devices removed from the PL to be independently monitored, with a focus on prices and the views of clinicians. Should independent monitoring find that either prices paid are higher than was previously the case and/or that clinicians believe their clinical choices have been significantly impacted, then the changes should be revisited. All stakeholders would surely agree that the outcome of any reforms must not be higher prices or reduced patient access to the best products.

In developing this feedback RACS received input from the Urological Society of Australia and New Zealand (USANZ). USANZ provided a number of comments relevant to urologists in particular:

> 'The definition of part A, B and C listings in the PL does not provide Urologists with enough detail to know where our high use items sit in this framework such as non-permanently implantable, non-biological items which are used commonly in Urology. Do these items (examples listed below) fall under Part C items "Medical Devices" OR do they come under "General Miscellaneous Category of Part A" (Consumable devices) which will be removed from the PL OR will they be eligible for listing under the PL under some of the single-use surgically invasive medical devices that meet other part A criteria for listing?
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> Examples cited:
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> - Ureteric stents
> - Laser fibres used in management of ureteric and renal stone disease
> - Ureteric access sheaths
> - Stone baskets for removal of ureteric and renal calculi used in ureteroscopy or pyeloscopy'

USANZ also provided this comment:

> 'There are certain surgical grafting materials used in the management of Peyronie's disease as well as complex renal surgery. The status of these grafting materials – some synthetic and some based on tissue harvesting, remains unclear.'

RACS has also been privy to feedback to this consultation provided by General Surgeons Australia (GSA). RACS endorses the GSA feedback and highlights in particular these comments:

> 'The fundamental shortcoming with the approach taken in the consultation process is that items required for specialty General Surgery procedures are bundled under 'Product Category 03 - General Miscellaneous', most of which have been flagged for removal as 'general use' items.
>
> Removal of these items does not recognise their essential nature in specialised General Surgery practice, compromises patient safety, and also means that Specialist General Surgeons would no longer be able to choose the product that is required for particular operations.'

RACS has also been privy to and endorses the feedback provided to this consultation by the Australian & New Zealand Society of Cardiac & Thoracic Surgeons (ANZSCTS), the Australian and New Zealand Oesophageal and Gastric Surgery Association (ANZGOSA), and the Australian and New Zealand Metabolic and Obesity Surgery Society (ANZMOSS).

RACS also notes the feedback to this consultation provided by the Australian Society of Plastic Surgeons (ASPS).

Thank you for allowing RACS to comment on the Prosthesis List reforms. We remain committed to working with Government and the private and public health sectors to ensure sustainability but without compromising patient outcomes.

Regards,

Prof. Mark Frydenberg

Councillor & Chair, Health Policy & Advocacy Committee

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