Chapter 4

Subsidised devices

Introduction

4.1 This chapter discusses cost effectiveness of subsidised devices and the effectiveness and accuracy of the billing code and Prostheses List.

Subsidised devices

4.2 The *Private Health Insurance Act 2007* (PHI Act) provides for mandatory benefits to be paid by private health insurers for a range of prostheses that are provided as part of an episode of hospital treatment (or hospital substitute treatment) where a Medicare benefit is payable for the associated professional service (surgery).

4.3 The prostheses for which a benefit must be paid by a private health insurer are listed on the Prostheses List. The Prostheses List is made under the PHI Act and the Private Health Insurance (Prostheses) Rules which require private health insurers to pay benefits for those prostheses. The arrangements for including products on the Prostheses List help to ensure that benefits paid by insurers are 'relative to clinical effectiveness'.[1]

4.4 The Prostheses List Advisory Committee (PLAC) advises the Minister about the listing of prostheses and their appropriate benefits in the Prostheses List. In making its recommendations to the Minister about which products should be included on the Prostheses List, PLAC considers the clinical effectiveness of the product including comparative cost and comparative safety.

4.5 The Prostheses List arrangements, the PLAC and its predecessor, the Prostheses and Devices Committee (PDC), were established to control inflation in private health insurance benefits paid for prostheses.[2]

4.6 The PHI Act provides for two categories of prostheses:

- no-gap prostheses: these prostheses are listed with a single benefit which health insurers are required to pay; and
- gap-permitted prostheses: these prostheses have both a minimum and maximum benefit listed. For these prostheses private health insurers are required to pay at least the minimum benefit.

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1 Department of Health and Ageing, *Prostheses List: Guide to listing and setting benefits for prostheses, Part 1 – Understanding the Prostheses Arrangements,* July 2010, p. 7.

2 Department of Health and Ageing, *Prostheses List Advisory Committee,* www.health.gov.au/internet/main/publishing.nsf/content/health-privatehealth-PLAC, accessed 12 October 2011.

4.7 The TGA noted that between 1999 and 2002, the growth of the cost of prostheses significantly increased the benefits paid by private health insurers. In response, the Government introduced a package of reforms to private health insurance that included new arrangements for listing products on the Prostheses List that provide for an evidence-based assessment of products and a centralised benefit negotiation process.[3] The PLAC terms of reference and business rules state that:

> The Prostheses List arrangements, the PLAC and its predecessor, the Prostheses and Device Committee, were established to control inflation in private health insurance benefits paid for prostheses. The Prostheses List plays an important role in ensuring the sustainability of the Australian private health insurance system, and helps to achieve the Government's policy objective of ensuring private health insurance remains affordable and accessible to all Australians.[4]

The Prostheses List

4.8 The Prostheses List contains 9 645 prostheses including cardiac pacemakers and defibrillators, cardiac stents, hip and knee replacements and intraocular lenses, as well as human tissues such as human heart valves, corneas, bones (part and whole) and muscle tissue.[5] The Prostheses List does not include external devices such as external breast prostheses, only surgically implanted prostheses.

4.9 The Prostheses List is managed by the DoHA which is also accountable for grouping devices and determining the benefit to be paid.

4.10 The Prostheses List is divided into two parts: Part A for prostheses and Part B for human tissue. A new Part C is being developed as a consequence of the Doyle Review. Part C will include items currently on the Prostheses List which do not meet the listing criteria but have proven clinical benefit, for example, insulin pumps. Part C items will include clinically effective and cost effective devices, such as those that are:

- not surgically implanted but with an internal part that is integral to the effectiveness and designed to combat a pathological process or modulate a physiological process; and
- surgically implanted devices to monitor a pathological or physiological process.[6]

4.11 The Prostheses List contains information on devices including billing code, product category, sponsor, product name and benefit(s). The billing code is a reference code allocated to a listed prosthesis and facilitates hospital invoicing

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3 Therapeutic Goods Administration, *Submission 18*, p. 8.

4 Therapeutic Goods Administration, *Submission 18, Attachment 5*, p. 1.

5 Therapeutic Goods Administration, *Submission 18*, p. 8.

6 Department of Health and Ageing, *Prostheses List: Guide to listing and setting benefits for prostheses, Part 1 – Understanding the Prostheses Arrangements*, July 2010, p. 15.

procedures and the payment of benefits by insurers. The billing code may be allocated to a single piece product, a system or set, or a pack containing different sizes of otherwise identical items. Sponsors are required to provide catalogue numbers for each component of a billing code. This allows users of the Prostheses List to understand what each billing code covers.

Prostheses List Advisory Committee

4.12 The PLAC was established on 4 October 2010 and replaced the PDC in response to the HTA Review recommendations. The PLAC is comprised of an independent chair, with members having expertise in current clinical practice, health insurance, consumer health, health economics, health policy, private hospitals and the medical device industry. In making recommendations, the PLAC considers advice from Clinical Advisory Groups (CAGs) and members of the Panel of Clinical Experts (PoCE).[7]

4.13 The main roles of the PLAC are to provide advice to the Minister about whether prostheses should be included on the Prostheses List. In doing so, the PLAC considers:

- whether a submitted or listed product is a 'prosthesis';
- whether the prosthesis under consideration has similar clinical function, effectiveness and safety compared with other prostheses included on the Prostheses List intended to treat similar clinical conditions;
- whether the cost of the prosthesis under consideration is similar to other prostheses included on the Prostheses List intended to treat similar clinical conditions; and
- whether the prosthesis under consideration should only be listed on a conditional basis, and, if so, appropriate conditions that should be applied to its listing.[8]

4.14 The PLAC also provides advice about grouping and description of prostheses. Grouping of prostheses enables a single (benchmark) benefit to be established for prostheses with similar clinical function, effectiveness and safety. Groups are being progressive developed by DoHA in response to recommendation 12 of the HTA Review (see below). The PLAC provides advice about appropriate benefits that are to be paid by private health insurers for prostheses included on the Prostheses List. Determination of the benefit is based on clinical effectiveness of the prosthesis compared with other listed prostheses providing similar clinical outcomes for comparable clinical circumstances. In addition, the PLAC refers concerns about the

7 Therapeutic Goods Administration, *Submission 18,* p. 8.

8 Therapeutic Goods Administration, *Submission 18, Attachment 5,* p. 2.

intrinsic safety of prostheses to the TGA and provides advice about other matters as requested by the Minister for Health and Ageing.[9]

Reviews of the listing and setting of benefits for prostheses

4.15 There have been two reviews of the prostheses arrangements for private health insurance. The first review was undertaken in 2007 by Mr Robert Doyle. The findings of the Doyle Review were overtaken by the HTA Review. The HTA Review commented that the Review provided 'an opportunity to revise current arrangements which impede progress for reform of Prostheses List activities to develop a more sustainable model for the future, as recommended by the Doyle Review to reduce regulatory burden (including costs) imposed on the medical devices industry'.[10] The HTA Review made three recommendations aimed at simplify administration of the Prostheses List by streamlining administrative processes and removing duplication:

Recommendation 10:

> That in order to reduce regulatory costs:
>
> (a) the terms of reference for the PDC and its subcommittees be revised by July 2010 so that it is clear that its assessments of prostheses only consider clinical effectiveness (including comparative cost and comparative safety); and
>
> (b) channels of communication between the TGA and PDC should be formalised to ensure that any concerns the PDC encounters regarding the intrinsic safety of prostheses are immediately referred to the TGA and dealt with appropriately.

Recommendation 11:

> That the PDC be restructured by July 2010 to ensure that its membership is balanced and:
>
> (a) includes individuals with expertise in current clinical practice, health policy and health economics;
>
> (b) includes representation from health consumers, health service providers, and the health insurance and health technology industries; and
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> (c) has an independent chair.

Recommendation 12:

> That the arrangements for the Prostheses List be changed by 2011, with appropriate consultation, to:

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9 Therapeutic Goods Administration, *Submission 18, Attachment 5*, pp 3–4.

10 Department of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009, p. 18.

(a) accept applications on a continuous basis, but still make the Prostheses List every six months;

(b) establish and maintain groups of products with similar clinical effectiveness;

(c) abolish the negotiation of benefits for individual listed products, and instead establish and maintain a single (benchmark) benefit for the products included in each group, with sponsors being required to accept this benefit in order to be listed;

(d) abolish the negotiation, setting or publication of maximum benefits, to eliminate the potential for gap payments for patients who have Private Health Insurance (PHI); and

(e) permit the establishment of new product groups (or sub-groups) where a sponsor establishes clear superiority of their product compared to those in an existing group.[11]

4.16 The Government accepted these recommendations. As noted above, the following matters have since been implemented:

- Recommendation 10: the PLAC has been established to replace the PDC, with revised terms of reference and new membership (recommendation 10a); and a communication protocol for the referral from the PLAC to the TGA of concerns regarding the intrinsic safety of prostheses or devices has been implemented (recommendation 10b);
- Recommendation 11: the PLAC replaced the PDC, with revised terms of reference and new membership; and
- Recommendation 12: the continuous acceptance of applications for the Prostheses List commenced on 2 August 2010 (recommendation 12a). A stakeholder consultation meeting was held in June 2010 and general agreement on the approach to implementation of recommendation 12b-e was reached. The Minister has approved this approach, including the establishment of a Consultative Committee, and phased implementations which will occur throughout 2010 and 2011. The Consultative Committee is continuing to meet to consider the proposed groupings and group benefits of products.[12]

11 Department of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009, p. 19.

12 Therapeutic Goods Administration, *Submission 18*, pp 11–12; Department of Health and Ageing, *Achievements since the release of the Health Technology Assessment Review*, www.health.gov.au/internet/hta/publishing.nsf/Content/achievements-1, accessed 12 October 2011.

Public health system

4.17 In the public health system, medical devices are supplied under agreements or tender arrangements between the supplier and the public hospital. Public hospitals also receive payments from health insurers for private patients who elect to be treated in a public hospital.

Issues

4.18 Submitters noted that the reimbursement of medical devices has been addressed in the HTA Review with the Review's recommendations being progressively implemented. Medtronic Australasia, for example, commented that 'some positive changes have been made'.[13] AusBiotech added that:

> With its revised membership and terms of reference, PLAC should assist with developing clinical evidence requirements for new Prostheses List applications as well as the development of procedures and models for assessing the cost effectiveness of medical devices in a more rigorous and transparent way.[14]

4.19 However, submitters also argued that a number of issues still remained to be addressed including addressing comparative cost effectiveness mechanisms, limitation of listing on the Prostheses List to implantable devices and the influence of gap payments on choice of device. Medtronic Australasia, for example, commented:

> Medtronic commends MSAC [Medical Services Advisory Committee] on the work it has done to develop a new framework for the MSAC assessment processes. However, we believe MSAC is experiencing significant teething problems with the new processes, resulting in a great deal of uncertainly for applicants who have applications in progress. This includes significant examples of "shifting goalposts", undocumented processes, partially implemented processes, poor communication of changes and processes, and expectations and lack of transparency. There are further improvements to be made here if Australia is to deliver internationally recognised good HTA practice.[15]

Cost effectiveness of subsidised devices

4.20 The cost effectiveness of medical devices is a significant issue for both the private and the public health care sectors. The benefits paid by private health insurers for prostheses for the 12 months to March 2011 were $1.3 billion, which represented 10.6 per cent of total benefits paid by health insurers during that period.[16]

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13 Medtronic Australasia, *Submission 14*, p. 8.

14 AusBiotech, *Submission 16*, p. 6.

15 Medtronic Australasia, *Submission 14*, pp 8–9.

16 Therapeutic Goods Administration, *Submission 18*, p. 8.

4.21 The Medical Technology Association of Australia (MTAA) commented that prior to the implementation of the recommendations of the HTA Review, cost effectiveness of implantable devices was assessed relative to comparator devices already on the Prostheses List. However, following the HTA Review, the grouping of products and the application of a benchmark benefit for each group of like products has been gradually implemented. The MTAA noted that the grouping mechanism employed to enable comparisons is 'a simpler and more appropriate approach than evidence-based assessments for reimbursements of products on the Prostheses List'.[17]

4.22 Other submitters raised the issue of the lack of comparative cost effectiveness of devices in relation to total benefits and costs. JJM commented that the cost effectiveness of devices should not be limited only to the device itself. Rather, total benefits and costs should be taken into account both within sectors and across sectors, for example, the utilisation of medical technology within the private sector may accrue savings to the Pharmaceutical Benefits Scheme.[18] JJM went on to state that it supported evidence-based medicine to achieve objectives including enhanced healthcare decision-making, access to appropriate technologies and optimal use of healthcare resources. JJM commented that:

> Individual patient needs should supersede short-term cost considerations, especially for the use of new treatments that potentially address unmet medical need and that may change the paradigm of therapy.[19]

4.23 JJM concluded that medical technology costs 'should not be judged in isolation or in silos for budget setting and budget holding'. However, JJM argued that this does not currently occur in the Australian healthcare sector and as a result there is 'non-realisation of cost savings within the overall expenditure on the healthcare system'.[20]

4.24 AusBiotech put a similar view and commented that the 'current system provides no incentive for medical practitioners and healthcare providers to look at the entire cost of the treatment over multiple admissions'.[21]

4.25 The need to assess comparative effectiveness was raised by the AHIA. The AHIA argued that assessment of effectiveness should consider both cost and clinical effectiveness of devices, with only devices which have been proven to be both more clinically effective and more cost effective should be listed. Dr Michael Armitage, Chief Executive Officer, AHIA, explained further:

> At the moment if someone brings in, for argument's sake, a stent to be put into a cardiac artery it is usually compared with another stent. It is,

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17 Medical Technology Association of Australia, *Submission 12*, p. 7.

18 Johnson & Johnson Medical, *Submission 28*, p. 20 and p. 24.

19 Johnson & Johnson Medical, *Submission 28*, p. 22.

20 Johnson & Johnson Medical, *Submission 28*, p. 24.

21 AusBiotech, *Submission 16*, p. 7.

> however, not compared on a comparative cost-effectiveness, or indeed comparative clinical effectiveness, basis with, for argument's sake, a coronary artery bypass graft. More importantly, it is not compared against, in this particular case, the use of optimal medical treatment—in other words, standard drugs that are used every day, and there is a trial in America, called the COURAGE trial, which seems to indicate that optimal medical treatment is better than either of those other two things. So there is a need for comparative cost-effectiveness.[22]

4.26 The AHIA concluded that:

> ...the medical devices should be competitively contestable to ensure ongoing growth. However, in ensuring an informed consumer, information should be readily available on comparing the best available HT alternatives.[23]

4.27 In relation to cost effectiveness, Medibank Private commented that within the Australian healthcare sector there is a fragmented approach with separate processes for medicines, procedures and devices. Thus the healthcare sector does not benefit from a global approach. In addition, Medibank Private noted that the take up of new technologies relies on suppliers introducing specialists to new medical devices or direct supply or hospitals. This, Medibank Private argued, is undertaken 'without any clinical evidence other than Therapeutic Goods Approval (TGA), or formal industry accepted process for reimbursement (such as that that exists for prostheses)'. A further matter raised was the change to the regulatory regime to contain costs. As a consequence, Medibank Private commented that approval, funding and use of new medical devices are 'complex and highly regulated'.[24]

4.28 While acknowledging the work of the HTA Review, Medibank Private argued that there are features of the current system which have 'led to unintended and unwanted outcomes for the Australian health system' and continue to affect the success of changes to existing arrangements. Medibank Private pointed to excessive costs for the health system as there is a lack of genuine competitive pressure; product selection that is predominantly determined by clinical choice without reference to cost effectiveness; and different classes of prostheses with widely differing benefits may be used with no clinical justification for the higher cost.[25]

4.29 Medibank Private outlined the features which are contributing to adverse outcomes. First, the scale and size of the Prostheses List is inhibiting attempts to group products on the basis of clinical effectiveness. For example, a review that involves around 2 500 products remains incomplete after almost two years. Medibank

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22 The Hon Dr Michael Armitage, Chief Executive Officer, Australia Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 1.

23 Australia Health Insurance Association, *Submission 20*, p. 3.

24 Medibank Private, *Submission 1*, p. 3.

25 Medibank Private, *Submission 1*, p. 4.

Private also noted that there is a major backlog of reviews of listings and benefits intended to be undertaken by the PDC, resulting in inconsistent benefits set for products with similar clinical effectiveness.[26] However, the AHIA commented that the 'grouping exercise is on technical rather than relative clinical effectiveness grounds'.[27]

4.30 Medibank Private went on to comment on practices in the private and public sectors and noted that the differing benefit setting arrangements for prostheses between the public and private hospitals sectors result in private health insurers having to reimburse prostheses at much higher levels in the private hospital sector where clinicians are not required or encouraged to consider cost effectiveness. While some differences reflect the level of training and product support between public and private hospitals, benchmarking indicates variation that exceeds this justification. In addition, there is a lack of emphasis given to considerations of cost effectiveness in the private sector which makes it difficult to encourage device suppliers (or sponsors) to develop and support generic prostheses. Medibank Private commented that 'while the regulatory framework needs to ensure that there are appropriate incentives for sponsors to invest in prostheses, innovations to develop generic products where they achieve the same or better results in more cost effective ways are similarly important'.[28] However, the AOA also commented that the price differential between the public and private sectors is not as great as it has previously been as procurement arrangements have now been undertaken by the States rather than individual hospitals.[29]

4.31 Medibank Private pointed to three further features which effect the current system:

- the encouragement of market competition between sponsors will help offset the market failures which exist in relation to prostheses, for example, information gaps for consumers who rely on clinical guidance, which is not required to reflect cost effectiveness considerations in any meaningful way;
- there is a paucity of information regarding clinical best practice to guide the choice of prostheses despite the work of the NJRR. As a consequence, the substitution of certain devices for more cost effective selections where clinical effectiveness is maintained is undermined; and
- there is a significant degree of discounting on prices actually paid by parties along the supply chain (sponsors, private hospitals, and possibly clinicians). Medibank Private argued that private health insurers, and ultimately the

26 Medibank Private, *Submission 1*, p. 4.

27 Australian Health Insurance Association, *Submission 20*, p. 9.

28 Medibank Private, *Submission 1*, p. 4.

29 Australian Orthopaedic Association, *Submission 5*, p. 2.

consumer, miss out on sharing in the discounts and no price disclosure or other comparable mechanism exists for sharing discounts.[30]

4.32 A final matter raised by the AOA in relation to costs generally is that there is no mechanism to take account of any increase in the value of the Australia dollar. Such a mechanism would ensure that the purchase cost of imported devices can be adjusted as the value of the dollar increases, thus providing benefits for consumers and the health sector.[31]

Prostheses List

4.33 As noted above, the Prostheses List was considered by both the Doyle Review and the HTA Review. The HTA Review recommended changes to the Prostheses List process. The Australian Private Hospitals Association (APHA) was of the view that 'it is too early in the process to make any definitive statements about how the new list is working'.[32] However, other submitters, while acknowledging that some changes have been implemented, argued that problems still remain. For example, Medibank Private indicated that there are 'inherent problems' in present prostheses systems which include:

- errors in prostheses listing of legislated requirements – Medicare Benefits Schedule/Australian Register of Therapeutic Goods (ARTG) numbers are absent, generic or incorrect;
- benchmarked benefits are generally overpriced compared to overseas examples and Australian public market;
- the constructs of the list are overly complicated with individual components of a prostheses being listed;
- no common identifier or coding system is in use. In addition, billing code identifiers for manufacturer codes are not publicly available;
- there is no audit of performance as a commercial instrument which creates unnecessary error rates and acceptance of poor practice;
- no benefit setting processes have been investigated or proposed post the HTA review; and
- the list has an inadequate classification system in that substitutable devices cannot be easily identified.[33]

4.34 These problems were also raised by other submitters with the AOA commenting on the accuracy of Prostheses List descriptors. The AOA stated that the

30 Medibank Private, *Submission 1*, p. 4.

31 Australian Orthopaedic Association, *Submission 5*, p. 2.

32 Australian Private Hospitals Association, *Submission 4*, p. 4.

33 Medibank Private, *Submission 1*, p. 5; see also Australian Health Insurance Association, *Submission 20*, p. 4.

relevant Clinical Advisory Groups are still identifying products that have been incorrectly listed in higher paying groups 'which companies rarely volunteer as an issue'. The AOA concluded that 'there are no penalties to ensure effective compliance and from the evidence it would seem that companies are not good at self-regulation'.[34]

4.35 Medtronic Australasia commented on the lack of sufficiently clear and detailed guidelines on the clinical evidence requirements for listing products on the Prostheses List. Medtronic Australasia argued that as there are no clear guidelines, there have been instances of what appears to be an inconsistent assessment of product application which 'greatly increases uncertainty for companies'. In addition, Medtronic Australasia stated that company requests for higher benefits for certain products due to clinical superiority are not currently being assessed as the criteria for superior clinical performance have yet to be developed.[35] The AHIA also commented that the grounds for superiority are inconsistent, not transparent and should be based on patient register performance.[36]

4.36 Issues with the billing codes were raised by the AHIA which argued that identification and coding standards remain fragmented across the industry and need to be addressed so that there is an effective link in the HTA information chain and that opportunities provided by the implementation of e-Health and the push towards a national product catalogue are captured.[37]

4.37 Dr Armitage, AHIA, commented that there is no billing code to catalogue link so that funders are unsure of what they are paying for. Dr Armitage called for action to be taken so that there is a link between the billing code and the Prostheses List.[38] This concern was supported by the AOA which argued that billing codes and catalogue numbers should be linked, 'as any one billing code can cover a multitude of catalogue numbers with inherent capacity for new technologies to be introduced into the billing code without scrutiny'. The AOA concluded:

> This linkage would not only enable more accurate auditing of devices and technology, but would enable device and technology companies to more accurately access their data through independent bodies such as registries. It would also bring a level of transparency to billing practices.[39]

4.38 The MTAA noted that DoHA is continuing in its efforts to ensure that product descriptions contained in individual billing codes are appropriately descriptive of the approved listing and that all entries have current registration with the ARTG. The

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34 Australian Orthopaedic Association, *Submission 5*, p. 2.

35 Medtronic Australasia, *Submission 14*, p. 8.

36 Australia Health Insurance Association, *Submission 20*, p. 10.

37 Australia Health Insurance Association, *Submission 20*, p. 4.

38 The Hon Dr Michael Armitage, Chief Executive Officer, Australia Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 1.

39 Australian Orthopaedic Association, *Submission 5*, p. 2.

MTAA commented that 'this is a burdensome task in respect to a list with over 9 000 entries but a necessary task which MTAA supports'.[40]

4.39 The Australian Private Hospitals Association commented that no concerns have been raised by its members in relation to billing codes.[41]

4.40 Submitters raised a range of other issues concerning the Prostheses List including the type of devices that may be listed. The MTAA, St Jude Medical and Boston Scientific Australia New Zealand (BSC) commented on the criteria for listing that requires the device to be implantable. It was argued that this requirement is unnecessarily restrictive and does not take into account new technologies. St Jude added that that the 'rigid and anachronistic' rules of the Prostheses List resulted in the most cost saving and effective clinical treatment is not delivered to patients.[42] As a result there is a cost to the health system. In addition, the MTAA argued that 'private patients do not always receive the benefits of technologies which are otherwise available on the Australian market'.[43]

4.41 BSC noted that 'increasingly technologies are being designed such as radiofrequency ablation, which if used, prevents the need for implantable devices, such as a defibrillator' which is a less invasive treatment.[44] St Jude Medical provided the example of its pressure wire which is used during coronary angiography. Where the pressure wire is used, the average number of coronary stents used is lower. However, as private hospitals do not receive any additional benefit for using a pressure wire, St Jude Medical stated that there is financial disincentive to use the device despite the significant decrease in heart attacks, death and overall cost. In the public sector, the uptake of this technology is higher as 'there are different financial drivers'.[45]

4.42 The MTAA acknowledged that the HTA Consultative Committee has terms of reference that will include examination of funding for cost-effective technologies that are not eligible for listing on the Prostheses List.[46] While BSC concluded that it:

> ...shares the concerns of health funds that we do not want to address these perverse incentives by listing every possible device. However, there is an opportunity to create an alternative list of surgical treatments requiring non-implantable devices to provide patients and doctors with the same certainty they enjoy from the Prostheses List.

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40 Medical Technology Association of Australia, *Submission 12*, p. 7.

41 Australian Private Hospitals Association, *Submission 4*, p. 3.

42 St Jude Medical, *Submission 8*, p. 3; see also Medical Technology Association of Australia, *Submission 12*, p. 7.

43 Medical Technology Association of Australia, *Submission 12*, p. 7.

44 Boston Scientific Australia New Zealand, *Submission 13*, p. 8.

45 St Jude Medical, *Submission 8*, p. 6.

46 Medical Technology Association of Australia, *Submission 12*, p. 7.

> BSC is working with the MTAA on a principled-based approach to creating a "Schedule C" for non-prostheses device treatments. As technologies evolve, there will be increasing need for a explicit list that enable doctors to provide the most appropriate treatment option for their patients. To do this, Australia will have to eliminate the perverse incentives inherit in the Prostheses List definition.[47]

4.43 St Jude also recommended that Part C of the Prostheses List should be revised to allow for devices such as the pressure wire to be listed.[48]

4.44 Two matters which affect the choice of medical devices were raised by AusBiotech. First, AusBiotech stated that the size of the gap payment required to be paid by a patient can influence the choice of device made by the medical practitioner. As a consequence, the sale of 'unselected' medical devices is impeded. Secondly, the revision of the Prostheses List twice per year can similarly effect the utilisation of devices. AusBiotech stated that when a new device is listed, benefits established for medical devices can universally change due to the new product being listed 'subsequently altering the gap payment required by the patient'.[49]

4.45 Medtronic Australasia noted that the development of a review and appeal processes for both the Prostheses List and for MSAC are progressing very slowly. As a consequence there is currently no mechanism for internal appeal and review of decisions and concluded that 'it is imperative that this be addressed as a matter of urgency'.[50]

4.46 Finally, the AHIA commented that there is no process proposed post the HTA review and no constructive papers have been commissioned or information released around which the industry can base decisions in regards to an ongoing process. The AHIA stated that 'this would include how benefit setting would work into the future, what would be the mechanisms for controlling benefit growth, and any indications of the establishment of further registries to ensure quality and safety'.[51]

Committee comment

4.47 A significant issue raised during the inquiry was the lack of assessment of comparative cost effectiveness of devices. It was argued that as a consequence, savings in other areas such as the PBS are not being identified. Evidence pointed to the fragmentation of the approval system across pharmaceuticals, devices and processes working against a global approach. The committee considers that more rigorous comparative cost effectiveness would benefit the healthcare sector, and there

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47 Boston Scientific Australia New Zealand, *Submission 13*, p. 9.

48 St Jude Medical, *Submission 8*, p. 6.

49 AusBiotech, *Submission 16*, p. 7.

50 Medtronics Australasia, *Submission 14*, p. 8.

51 Australian Health Insurance Association, *Submission 20*, p. 4.

is some way to go before this can be implemented. However, the committee considers that once the recommendations of the HTA Review have been fully implemented, the strengthening and streamlining of processes will allow for comparative clinical and economic evaluations by MSAC. These issues of clinical effectiveness were also considered in chapter 3

4.48 The committee notes the changes being made to the Prostheses List as a result of the HTA Review. While there remain some concerns with the Prostheses List, the committee considers that many will be addressed as further changes are made. In relation to the restriction of listing of implantable devices on the Prostheses List, the committee notes that a new part to the Prostheses List (Part C) is being developed which may address some of these concerns.