AusBiotech's submission to the Senate Community Affairs References Committee Inquiry into Price regulation associated with the Prostheses List framework

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AusBiotech is pleased to make a submission to the Senate Community Affairs References Committee (Committee) Inquiry into the matter of 'Price regulation associated with the Prostheses List (PL) Framework'. Our submission represents a collation of comments and submissions from AusBiotech members engaged in delivering economic benefits to Australia through the commercialisation of biotechnology and the life sciences.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes medical technology, bio-therapeutics, food technology, industrial and agricultural biotechnology sectors. The industry consists of an estimated 900 biotechnology companies (400 therapeutics and more than 500 medical technology companies) and employs in excess of 45,000 Australians.

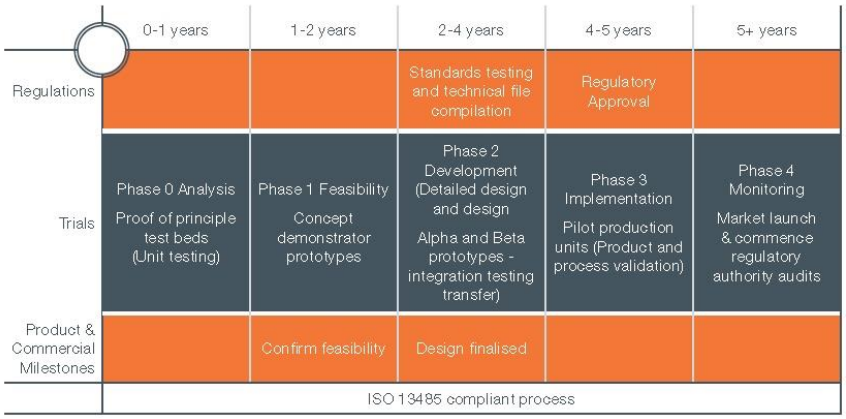
In Australia, with a few exceptions, these companies are typically young and small, competing globally for investment and market share. The industry is advancing rapidly into new fields of science and engineering. It is a highly-innovative sector pushing the boundaries in advanced manufacturing, using highly-skilled labour and distributing to global production chains and specialised markets.

Typically, the research, publicly funded in hospitals, universities or medical research institutes or privately developed by surgeons, should it show promise as an implantable device, enters a translation process that relies on the attraction of private money. Given the Australian government does not bring products to patients/market, the public/private compact is activated. The task ahead, in the Australian context, is to leverage the IP rights and attract the hundreds of millions of dollars required over the five or more years of the clinical trials and development that is takes to reach regulatory approval.

While the PL is often thought to be applicable only to multinational companies, AusBiotech members are typically small to medium enterprises (SMEs) locally developing new technologies, many of which will be destined for inclusion on the PL. Many of these companies have one or few devices in development.

The figure below shows the typical development pathway. It is at the end of this process that the prosthetic is considered for the Prostheses List, and can result in a further two to five years to be included on the PL.

Schematic showing typical development pathway, specific to a medical device



AusMedtech, an AusBiotech program, is dedicated to the representation, development, growth and prosperity of the Australian medical technology (device and diagnostics) industry.

The AusMedtech Health Economics Expert Panel (HEEP) is an expert group from amongst AusBiotech's member organisations, who provide advice on matters including the health economics of medical devices. The HEEP members have reviewed the consultation document and the comments have bene collated by AusBiotech to form the basis of this submission.

AusBiotech is committed to supporting a workable solution to reform of the prostheses benefits framework. We would like to recognise and commend the Department of Health for their continuing efforts to work with industry in this area. As the Committee would be aware the Department of Health has initiated a process to develop and implement a framework for reform of the prostheses benefits and AusBiotech has contributed to the initial consultation phase of this process. AusBiotech encourages the Committee to support and endorse the work of the Department of Health to undertake this reform in this area.

Introduction

AusBiotech members are concerned about a perceived lack of recognition of direct and indirect impacts from prostheses benefits reform on Australian innovation, research and development, manufacturing and importation in the medical technology sector. We support reform that fully considers the broader implications of modification of the Prostheses List (PL), however, we are apprehensive that the development of Australian research and industry in the medical technology sector will be collateral damage in pursuit of minimising cost if a well-constructed and considered reform is not achieved.

The key themes, comments and issues of industry include:

- The opportunities to damage Australian companies' developing innovative prosthetic technologies are great if pricing framework changes are poorly considered and implemented;
- Less than 15% of reimbursements paid by private health insurance (PHI) are for products on the prostheses list, making any substantial cost saving to private health insurance minimal;
- The biggest opportunity for cost savings is in reducing red tape and redundancy across the PL application and evaluation processes;
- Australia's private and public healthcare systems are different and the prices of prostheses in each cannot be directly compared;
- International healthcare systems are different to the Australian healthcare system and therefore cannot be directly compared to infer benchmarks;
- Items outside of the current criteria for inclusion on the PL should be considered in the broader heath care context, to provide costs saving and/or improved care. This would involve revising the inclusion criteria for the PL to allow products that don't currently fit the criteria;
- The value-based pricing model is the most suitable method for establishing the benefit for innovative products; and
- Any changes should be phased in over reasonable timeframes and managed sensitively, so as to allow sponsors to adapt.

Responses to address the terms of reference

a. the operation of relevant legislative and regulatory instruments

AusBiotech suggests that there is opportunity to improve the operation of the legislative instrument 'Private Health Insurance (Prostheses) Rules 2016 (No.4), Part A-Prostheses List (Category 07-13)' through review and enhancement of the constitution and the operation of the Clinical Advisory Groups (CAGs). Under their terms of reference, the primary role of the CAGs is to advise the Prostheses List Advisory Committee (PLAC) and the Department of Health on applications to list medical devices and their clinical effectiveness for listing on the PL.

Given the increasing sophistication and complexity of medical technology we contend that the current membership of the CAGs lack the breadth of expertise to adequately assess clinical effectiveness and cost effectiveness. We acknowledge that current members of the CAGs are expert clinicians in their field. However, sponsor applications include highly-technical information and clinical data in specialist areas such as biomechanics, engineering, material science, clinical trials, statistics and health economics, which are not areas of expertise of the CAG membership. Some decisions are perceived by industry to be arbitrary and inconsistently applied, and CAG process as a whole is opaque to sponsors, suggesting that a more transparent and rigorous process may be constructive.

To improve the quality and scientific rigour of advice provided by the CAGs we recommend that the CAG membership be extended beyond clinicians to include, or at a minimum have access to, independent experts in the areas noted above to constitute a truly multi-disciplinary committee, reflective of the applications the CAGs are tasked to assess. In addition, we recommend enhancing the regulatory rigour of the guidelines under which the CAGs operate to facilitate a science- and evidence-based clinical evaluation resulting in improvement the quality of decision-making.

b. opportunities for creating a more competitive basis for the purchase and reimbursement of prostheses

AusBiotech endorses the modernisation of the PHI framework of which identifying opportunities for a more competitive basis for the purchase and reimbursement of prostheses is one component. As part of this process we acknowledge the work of the Industry Working Group (IWG) on Private Health Insurance Prostheses Reform, which examined, engaged in stakeholder consultation and, in its Final Report, provided advice to the Department of Health on creating a more competitive basis for the purchase and reimbursement of prostheses. Further, we support the Department of Health project to research pricing models for medical devices and development of potential options for a future benefits setting framework for prostheses being conducted by the Centre for Health Policy at the University of Melbourne.

1. Principles for underpinning prostheses benefits reform

The value proposition of PHI is to provide consumers with certainty of access to medical treatment when and where needed. This includes choice of doctor, hospital, time and technology. Consumer research has shown that issues of concern are the rising cost of insurance premiums, expense, affordability and lack of value for money. To address consumer perception AusBiotech supports research and stakeholder consultation to investigate reforms to the current model underpinning prostheses benefits setting and propose the following guiding principles:

- Maintenance of clinician and patient choice of prosthesis;
- Maintenance of no out-of-pocket payments for prostheses by patients;

- Management of any model is practical and least burdensome for all stakeholders, including government, clinicians and industry;
- Costs associated with administration of any model are sustainable;
- Totality of the service delivered is taken into account when determining the value of the prosthesis benefit for a product, i.e., not only 'clinically relevant requirements', as mentioned by the IWG, but also other aspects of service (e.g., education provided), the relative size of the private market, attractiveness of Australia for launching new technologies, etc;
- Recognition and consideration of intrinsic differences in the structure of domestic public and private procurement care systems. In particular with respect to the diversity of the suppliers in terms of scale, type and range of products supplied;
- Allowance for a benefit premium to be applied to a product with demonstrable clinical or economic benefits that improves patient outcomes or hospital quality measures;
- Pricing reviews should be an intrinsic component of the framework;
- Recognise and support Australian innovation and development of new technologies by incentivising the adoption of new and improved medical technologies with demonstrable patient benefit;
- Timelines for the implementation of benefits reforms should allow the market appropriate time to adjust;
- With an increasing trend towards bespoke products some consideration should be made to products that are custom made with recognition that these products' mean data is available only post-market, not pre-market;
- Sources of data used to research the competitive basis for purchase and reimbursement of prostheses and devices should be credible and protect commercially sensitive information; and
- Policy reforms should avoid creating barriers to entry and reducing competition.

2. Adjunct costs and considerations

Industry feels strongly that the evaluation of opportunities for creating a more competitive basis for the purchase and reimbursement of prostheses should consider the benefit paid for an item on the PL is not simply the price of the device itself. AusBiotech supports reform that recognises and ascribes clinically relevant costs associated with the full service offering for the medical device and the after-service component for life-cycle management of the medical device over its lifetime. It may, and usually does, include adjunct services to consider when setting benefits including, provision of loan kits, consumables, supporting hardware and software, application and clinical support and more specifically below:

2.1. Training costs and in-theatre assistance

Training costs and in-theatre assistance are required to ensure that devices are used appropriately and safely, it is often necessary that suppliers provide training on the use of their product (particularly for new products and/or new trainees).

It is an acknowledged and published concept that medical devices have an associated "learning curve". This variable is specific to medical device as opposed to pharmaceuticals and therefore is not identifiable in the PBAC model. This variable differentiates the two sectors.

It is a sponsor responsibility to train professionals on the use of the device as per sponsor obligations (aligned to an ARTG) to ensure the performance of the device is optimal for patient outcomes – intra-theatre/doctor-to-doctor training.

For some Class III devices, there is a concurrent obligation that the TGA requires from sponsors for heightened post market surveillance of which training is acknowledged as one way to ensure device performance is matching the proposed clinical efficacy.

Surgeries involving implanted medical devices will often be attended by trained sales representatives upon the request of surgeons (particularly for difficult cases) and theatre staff. The representatives are able to respond to questions related to product selection, sizing, manipulation of the delivery system etc. Higher levels of training and in-theatre support are often required for devices with a higher degree of technical difficulty or where devices are used infrequently or in low volume.

Example of training associated with supply of a medical devices: Endovascular graft

With the introduction of advanced endovascular grafts, to ensure patient safety, the supplier will provide specialised training courses to a doctor who has not used the device before (courses cover patient selection, case planning/sizing etc.). Once the courses have been completed, the supplier will contract an experienced vascular surgeon (proctor) under a fee for service basis to provide guidance to the doctor during initial use of the device. The proctor may need to attend several cases until the doctor is confident with the use of the device. The cost to the supplier would include consultant fees for training sessions and proctor fees per case (based on complexity plus travel costs).

Ongoing, upon the request of doctors, the supplier will provide consultations for advanced case reviews and the supplier's trained sales representatives / clinical specialists will attend most surgeries. The representatives are able to respond to questions related to product selection, sizing and manipulation of the delivery system. As representatives have attended many cases previously, they are also able to provide insight into what other doctors have done in similar clinical scenarios.

2.2. Freight and consignment management

Hospitals prefer stock to be kept on consignment. Therefore, this is more costly for suppliers as the manufacturer is required to keep the same stock in multiple locations rather than in one or multiple central warehouse/s (a single warehouse may be problematic given Australia's geography). Further, as manufacturers are exposed to greater financial risk due to stock holding cost, stock management and stock write off because of the requirement to keep increased inventory in-country.

Given that absolute sizing for some devices is only known once a procedure is commenced, a surgeon may request multiple sizes to be on hand for the procedure and then they will return the unused stock after the procedure. As this can occur across the entire country on any given day, the company is required to keep excess stock to meet surgeon demands, leading to increased handling and inventory costs.

It should also be noted that freight tends to be by air, which is more expensive but expedites product delivery to patients and the environmental aspects are easier to control.

2.3. Post-implant monitoring of active implantable devices

Active implantable devices require the provision of service and support for the life of the device and or life of the patient. The cost of this support, which may include proprietary hardware and software adds to the benefit level.

Example of scop of service

Excerpt from the scope of Service and Support requested for cochlear implants (active implantable devices) as defined in the Request for Tender by The Royal Victorian Eye & Ear Hospital (November 2016).

The scope of Service and Support that may be required:

- Provide troubleshooting services and long term patient management.
    - Long term device Mapping (programming)
    - Device trouble shooting and repairs
    - Provision of loan processors while the patients is being repaired or replaced
    - Liaising with Australian Hearing and the National Disability Insurance Scheme for funding of processor upgrades and the provision of clinic support documentation.
    - Sale of sound processor accessories
- Deliver the quantity of the implant systems at the level necessary for the Hospital's requirements for public and private patients.
- Deliver hands on education and training packages to ensure clinical audiology staff develop the specialist skills required to operate the information technology systems and software packages.
- Provide regular updates and training to the Cochlear Implant clinic staff, surgeons, theatre staff.
- Provide instruments required for surgical procedures.
- Provide the clinic with sufficient free back up implants to support difficult theatre cases.
- The hospital will be provided free of charge, all hardware that is required to undertake device programing, including cables, programming interfaces/units etc.
- The provider will provide free of charge, 5 spare functioning sound processors which will be available to the clinic to enable troubleshooting as well as free demo kits to be used in the clinic for patient counselling.

- Ensure that implants and processors are received within agreed timelines to facilitate surgical sessions and clinic functions. This may require short turnaround times for urgent surgical cases
    - Provide implant systems to the Hospital within 5 working days of the order being placed.
    - Provide cochlear implant to the hospital within 24 hours of the order being placed for urgent surgical cases.

3. Pricing methodologies/models

In understanding how prostheses benefits should be set, we suggest that the costing model would be pivotal to the reform process and provide below a discussion on possible models.

There is no existing model that could be fitted to the circumstances and therefore it is our recommendation that two or more models be adapted to meet the needs of Australia's specific environment.

3.1. International reference pricing:

This model requires the collection of prices of the proposed item from relevant countries e.g. Japan, UK, US, France, Canada. The formula is based on taking the median/average of these prices, converting the proposed item according the published foreign exchange rates and adjusting by a defined factor.

We suggest that consideration of a number of factors, outlined below, is important when comparing pricing in Australia to international prices:

3.1.1.Wages

Wages (particularly when super, payroll tax, leave entitlements etc. are factored in) are higher in Australia than many countries.

3.1.2.Market size

Generally, sales per company representative are lower in Australia (due to smaller populations/ hospitals, geographical spread and high service expectations). For some products, suppliers will need to carry multiples of each size as they are emergency items (for example one supplier offers a range of over 500 endovascular graft sizes available for sale in Australia). Smaller markets have higher product write-offs as the turnover will not be as frequent (the shelf-life for many products is only three years).

3.1.3.Regulatory

Although the Australian regulatory system enables companies to leverage off their EU regulatory approvals, there is still a fair degree of regulatory burden (management of individual submissions and reporting requirements).

In addition, once a device is listed on the ARTG the product can be sold directly into the public hospital system. However, if the sponsor wishes to apply to the PLAC for the device to be included on the PL independent clinical data is required. As it is commonplace that one to two years of independent data is required, access to the prostheses benefits can take up to five years. When the time taken for the PLAC process is taken into account, this can represent up to a quarter of the lifespan of a device. AusBiotech suggests that consideration of this cost burden to sponsors as a result of the delay to prostheses benefit for devices should be considered when determining the value of the product.

3.1.4.Currency fluctuations

As the majority of medical devices are imported, suppliers need to take into consideration the volatile Australian dollar. Suppliers cannot easily adjust pricing (prices are fixed on the PL or via tenders/price file negotiations, which may last 1-3 years).

Consideration of the uniqueness of Australia's healthcare system compared to other international systems is critical with respect to key criteria that influence the value of the prostheses benefits, including the market structure, market segmentation, procurement structure, geographic spread and lower volume due to Australia's comparatively small population. Manufacturers who supply in Australia forgo any autonomy in setting prices once included on the PL and are not able to adjust prices to respond to typical market fluctuations and movements.

3.2. Domestic reference pricing for comparable devices

This formula is based on the median/average of prices adopted by public hospitals, adjusted for disparity in market size/sales volume and service add-ons in the private sector with some degree of price disclosure necessary. Domestic reference pricing could be used to benchmark but it is not indicative of the value of the full service associated with the medical device over the life time of the product.

To enable timely access to a choice of prostheses, we suggest that there is a simplified process for the addition of comparable products (those not making any claims of superiority that fit into an existing therapeutic group). We understand that a similar model is utilised in Japan. However, we do not support this process for the determination of the prostheses benefits for new innovative products (refer to 3.5 Value based pricing for new, innovative devices).

3.3. Full (mandatory) price disclosure (i.e. PBS model)

This model has the potential to improve price transparency and reduce rebates for existing categories of products. However, the implementation and administration of this system would be expensive and our members have expressed concern that the burden of these costs would be passed on to industry.

Price disclosure for devices cannot be compared to pharmaceuticals (PBS model) and is less appropriate to devices because of the differences in the operations of the supply chain.

3.4. Cost plus price

Under this model the price is based on the cost of production, together with allowances for the R&D content, and for marketing and management of the product. Essentially this is the model that in the past has been used to determine the prostheses benefit. The disadvantages of this model are that it is difficult to attribute costs across the diversity of devices on the PL.

3.5. Value based pricing for new, innovative devices

Benefit premiums, defined on the basis of value based pricing, are applied to a product with demonstrable clinical or economic benefits that improves patient outcomes or hospital quality measures.

Current benefit setting processes are 'opaque' and do not appear to be related to conventional health economic principals. The rebate for an item deserving a new category could be set on a comparative cost-effectiveness basis - not necessarily requiring cost-utility analysis, but at least evidence of incremental clinical benefit against which an appropriate price might be gauged (taking into account cost offsets impacting health insurers).

To address some of the issues with the current model in establishing value for new innovative devices AusBiotech suggests that the research from this project could be applied to design a transparent set of criteria for evidence to establish value.

AusBiotech supports consideration of the unique qualities of medical devices in the process of reform. There are many components that attribute to the cost of a device and this ought to be reflected in the pricing model. While there is no existing model that would be ideal model 4.5. Value based pricing for new, innovative devices would assist.

4. Pricing reviews

Pricing reviews should be an intrinsic component of the framework and should be targeted particularly at products that have been on the market a number of years, have high volume and multiple suppliers.

Factors to consider for the pricing review include:

- Material changes in cost of production
- New clinical evidence that demonstrates additional benefit (value based)
- Depreciation of R&D
- Consumer Price Index (CPI)
- Volume – economies of scale
- Frequency: e.g. every 2 years for comparable products; every 4 years for new innovation
- In-theatre and on-going service and support required for devices

c. the role and function of the Prostheses List Advisory Committee and its subcommittees

AusBiotech is supportive of the reconstituted Prostheses List Advisory Committee (PLAC) under the newly-appointed Chair, Professor Terry Campbell AM. We are encouraged by its broad representation and expertise within the Committee. The PLAC has developed the Reform Work Plan to address the recommendations outlined in the IWG Final Report, and we look forward to improvements to the process

of application, evaluation and decision-making as well as transparency for sponsors listing products on the PL.

AusBiotech's comments on improving the function of the CAGs are included above under Term of Reference (a).

d. the cost of medical devices and prostheses for privately insured patients versus public hospital patients and patients in other countries

AusBiotech's comments on the cost of medical devices and prostheses for privately insured patients versus public hospital patients and patients in other countries are included above under Term of Reference (b).

e. the impact the current Prostheses List Framework has on the affordability of private health insurance in Australia

As the PL framework is only one component of the public health insurance (PHI) offering in Australia we strongly recommend that any reforms to improve affordability of the PHI are applied to the whole PHI offering, to ensure the sustainability of PHI into the future. Noting that the products on the PL constitute less than 15% of PHI reimbursements.

f. the benefits of reforming the reference pricing system with Australian and international benchmarks

AusBiotech's comments on the benefits of reforming the reference pricing system with Australian and international benchmarks are included above under Term of Reference (b).

g. the benefits of any other pricing mechanism arrangements, including but not limited to those adopted by the Pharmaceutical Benefits Scheme, such as:

i. mandatory price disclosure,

ii. value-based pricing, and

iii. reference pricing

AusBiotech's comments on the benefits of any other pricing mechanism arrangements are included above under Term of Reference (b).

h. price data and analytics to reveal the extent of, and where costs are being generated within, the supply chain, with a particular focus on the device categories of cardiac, Intra Ocular Lens Systems, hips, knees, spine and trauma

Caution is recommended when reviewing price data and analytics to be assured that the information is credible, comparable and verifiable.

i. any interactions between Government decision-making and device manufacturers or stakeholders and their lobbyists

Consultation between Government and stakeholders is fundamental to Australia's system of democracy. Opportunities for engagement with Government should be encouraged, allowing Government to make informed decisions on behalf of Australians. In particular Australian innovators, researchers, developers and manufacturers in the medical technology sector need involvement in the consultation, to ensure that they are not unfairly disadvantaged in the process to reform the prostheses benefits framework.

j. any implications for prostheses recipients of the National Disability Insurance Scheme transition period

AusBiotech has no comment.

k. other related matters

1. Maintaining the sustainability of Australian medical technology organisations

Structural and administrative changes to the Prostheses Benefits framework are likely to have a larger negative impact on smaller Australian innovators, developers and manufacturers of medical technologies rather than on large multinational companies that are more easily able to absorb the costs associated with reforming the framework. This in turn will impact the development and delivery of new and improved technologies for patients. Therefore, we recommend that due consideration be given to ensure that the viability and sustainability of the Australian medical technology companies when developing and implementing reforms.

2. Expanding the eligibility criteria for the Prostheses List

The eligibility for inclusion on the PL generally requires a product to be both registered on the Australian Register of Therapeutic Goods (ARTG) and surgically implantable. However, we suggest that the current eligibility criteria for the PL do not reflect the significant advancements and innovations in medical technology.

The trend towards personalised medicine will manifest in an increase in customised devices that will not be registered on the ARTG. We recommend expanding the eligibility criteria for the PL to include medical devices that do not have an ARTG, such as surgically implanted 3D printed and customised medical devices.

Significant technological developments in medical devices have resulted in non-implantable devices that deliver demonstrable clinical benefits and cost effectiveness over existing procedures for the same indication. As an example, the clinical and economic evidence for ablation catheters, a non-implantable device to treat atrial fibrillation, shows improved health outcomes for patients and long-term cost savings to the health system overall. We recommend expansion of the Part C of the PL to include selected non-implantable devices with have demonstrable clinical and economic outcomes.

Conclusion

AusBiotech thanks the Committee for the opportunity to submit comments to the Inquiry into 'Price regulation associated with the Prostheses List Framework'. We support reform of the prostheses framework with consideration that the principles and analyses of proposed models outlined in Term of Reference (b). We suggest that there is no existing model that would be an ideal model, however, recommend that 3.5. 'Value based pricing for new, innovative devices would assist'.

Any reform or change has the capacity to damage Australian companies developing new technology and slow or remove their capacity to sustainably deliver or innovate to improve patients' health outcomes. We also strongly recommend that the Inquiry consider the impact on the prosperity and sustainability of the Australian medical technology sector as this industry has less agility to absorb the costs and management of reforms. Given products on the PL constitute less than 15% of PHI reimbursements and

cost reform is unlikely to have significant savings for PHI it is important that any reform be fully considered.

The application and evaluation processes for listing on the PL could be improved to provide legitimate savings if red tape is cut.

Private and public healthcare systems in Australia are not comparable and nor can Australia's healthcare system be compared with international healthcare systems for benchmarking.

AusBiotech recommends the modernisation to reflect technological advances in the medical devices sector via expansion of the PL to include certain non-ARTG listed products and non-implantable devices.

The real impact of ill-considered changes is that they are likely to make it harder for medical technology companies to develop and deliver new prostheses to patients in Australia, and further challenges the sustainability and growth of the emerging Australian medtech industry.