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Dear Mr Palethorpe

**AHIA response to the Inquiry into the**
**Regulatory Standards for the Approval of Medical Devices in Australia**

The Australian Health Insurance Association (AHIA) welcomes the opportunity to comment on the Community Affairs References Committee terms of Reference to the Inquiry into the Regulatory Standards for the Approval of Medical Devices in Australia.

The AHIA represents 23 Private Health Funds, which collectively insure approximately 94 per cent of the 11.5 million Australians who hold some form of private health cover.

The AHIA has collated comments from our member funds in relation to the Inquiry. Some insurers also intend to make individual submissions direct to your consultation process.

**AHIA and Medical Devices**

The AHIA is actively involved in ensuring the effectiveness of regulation and re-imbursement systems for Health Technology .We have two nominated members on the Prostheses Listing Advisory Committee (PLAC) plus a Member on the Health Technology Advisory Consultative Committee. We also facilitate an AHIA theatre banding committee which is charged with setting re-imbursement guidelines in covering costs incurred by members in an operating theatre environment. We are involved in information sharing with industry groups involved with medical devices such as sponsors/manufacturers, clinical and hospital. We are involved with broader health technology issues as it impacts on ancillary services supplied to our funds members.

We welcome the Australian Government Senate inquiry into the regulation of medical devices and believe there are real opportunities to improve the regulatory and reimbursement processes which will benefit the health care industry.

**AHIA's Response to the Terms of Reference:**

**"The regulatory standards for the approval of medical devices in Australia, with particular attention to devices with high revision rates, and in undertaking the inquiry the committee consider: "**

Note: High revision rates per se do not indicate a failure of the device for a number of reasons. The device, depending on the complexity of its interaction with the patient can suffer in performance due to the clinical interaction, patient interaction or the fact that it is the best outcome offered by the technology at the time. As such revision rate data needs to be contextualized by knowledgeable individuals from within the clinical professional bodies or from another area of the health system. Suffice to say, high revision rates should be a target where improved outcomes can be gained from either improvements in Health Technology, clinical processes or up &downstream life style adjustments. However, the fact that devices can be placed onto the Register without rigorous Clinical Testing (which in turn may lead to High Revision Rates) should be a matter of the greatest concern.

**(a) The role of the Therapeutic Goods Administration in regulating the quality of devices available in Australia;**

Quality tends to be a subjective term unless clearly qualified. The TGA's primary role is to regulate first for safety and then efficacy (fit for purpose). It is considered clearance of these standards is a reflection of quality. However, the accepted norm is that quality is expressed beyond this point when looking at clinical and cost effective performance of the devices. To a large extent the TGA does not currently take this into account.

The TGA quality assessment is in terms of the technical performance of a sponsor to deliver the device consistently as assessed primarily through documentation assessment processes such as Good Manufacturing Process Audits, etc. The TGA does not assess quality on the basis of clinical outcomes. Its primary role is as gatekeeper to ensure no unsafe or non-efficacious devices are allowed onto the Australian Market. Efficacious in the sense that the device is fit for the purpose it has been designed, regardless that that purpose may be clinically and cost in-effective.

Should the TGA's role be expanded to consider clinical and cost effectiveness? Yes & no. Yes for clinical effectiveness considering the limited quality resource that Australia has in HT assessment it then makes sense to incorporate the clinical effectiveness assessment together with the efficacy assessment for regulating market entry. The intention of such a combined process would not be to limit entry to market based on lack of assessable clinical evidence but to group similar technologies based on the level of evidence available which will then allow the market to negotiate an appropriate cost based on the potential clinical risk being absorbed.

The cost effectiveness needs to factor in the risk but still needs to be a separate process from the market entry processes as its scope is much wider than that expected from the TGA and could lead to a potential conflict of roles. There are obvious synergies available with information sharing between the TGA and reimbursement systems which were only superficially highlighted by the HTA Review.

Quality of performance draws into the issue of approval of devices based on their efficacy in a particular clinical application. Our understanding is that the clinical fraternity does not restrict its

choices of device to the identified application. However, the degree of actual and potential off-label use impact on quality outcomes is not known in any specific device setting.

**(b) the cost effectiveness of subsidised devices;**

Refer above as cost effectiveness currently is and should be outside the TGA's scope. The market and re-imbursement systems are accountable for making such choices. i.e. PBS,MBS,PLAC, Public State purchasing bodies etc.

Unfortunately there has been no systematic analysis of potential re-imbursement or payment systems for Device Health Technology in Australia. Devices are different from drugs on a number of levels but most importantly the structure of the drug market is that a single payer (Australian Government) is attempting to leverage this position with large Pharma to get world's best pricing. As the product per se requires fewer augmented components than devices, this leverage is possible. However, a significant component of improved cost benefits for devices comes from the value add as it were - training, tooling, service support, warranty etc. Hence a viable contestable market at the coal face needs to be maintained and encouraged.

Re-imbursement systems were only briefly considered in the scope of the HTA review and a simplest pathway of an attempted emulation of the PBS pricing processes appears to be the pathway pursued by the DoHA for devices in the regulated private health care market (Prostheses Listing). This may explain the recommendation to remove negotiation as a process, as by its nature it creates the perception of a lack of transparency. This leads to a minimum cost approach where the lowest benefit accepted becomes the benchmark. There is currently no analysis undertaken between competing technologies at this level, the devices being merely grouped based on similar technological traits and therefore clinical outcomes.

There is a great need for a COMPARATIVE EFFECTIVENESS assessment (both Clinical and Cost effectiveness) of any new device prior to listing for use in Australia, with listing only to be allowed once the newly proposed device had been proven to be both more clinically effective, and more cost effective. If such a suggestion were to be opposed, one could ask those opposing it why they would want Australians to be subjected to devices which had been proven to be less clinically effective and less cost effective than devices already available? Such a process would ensure that any device to be listed was only listed once it had been proven to be superior to presently available devices on both counts

State and territory purchasing processes vary but are generally more commercially focused ensuring extraction of value relating to the value added components. This generally involves the users undertaking field trials as part of the selection process where appropriate.

The AHIA believes 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.

**(c) the effectiveness and accuracy of the billing code and prostheses list;**

The Prostheses List (PL) only operates in the private health care market and only for implantable prostheses which the government subsidizes to the tune of the 30% rebate. The PL operates as a pricing mechanism for these devices in the market and as such has little involvement in assessing the

ongoing effectiveness and performance. There is no flag or indicator to a billing code identified as being subject to an alert or recall and benefits are not adjusted based on industry feedback as to the device's performance. If this option were to be pursued, there is considerable scope for improvement, via the coding and identification processes between the TGA, PL and any patient data registers that would potentially pick up on these points.

The recent HTA has seen significant changes to the PL process, in particular the accelerated grouping and benchmarking exercise. The inherent problems of the PL and listing processes, which were not addressed prior to exercising the HTA Review recommendations, still exist.

i.e.

a. Errors in PL of legislated data requirements – MBS/ARTG numbers absent, generic or incorrect.
b. Current benefits and new benchmarks being overpriced vs other developed and Australian public markets
c. Overly complicated constructs with every nut, bolt and washer listed.
d. Billing code identifiers to manufacturer codes not being publicly available.
e. No audit of performance as a commercial instrument and that of the error rate and acceptance through the process etc.

Across industry, identification and coding standards remain fragmented and need to be addressed in ensuring an effective link in the HTA information chain. The implementation of e-Health and the push towards a national product catalogue does offer the opportunities which need to be captured. Similarly in capturing the whole of episode costs, linkage to the other relevant re-imbursement tools needs to be investigated e.g. Device specific MBS usage

Finally, of concern to the AHIA is that no processes have been proposed post the HTA review and no constructive papers have been commissioned or information released around which the industry can base a sensible decision in regards to an ongoing process. 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.

**(d) the processes in place to ensure that approved products continue to meet Australian standards;**

It is assumed that standards refer to the safety and efficacy standards of the devices approved for sale into Australia.

As is the case with clinical matters relating to health, continuance of Health Technology performance assumes we have suitable monitoring, diagnostic and treatment services to pick up on any episodes of failing Health Technology. Where the Health Technology is within the acute care environment, facilities have excellent processes to monitor and track their investment in Health Technology. The difficulty occurs when this Health Technology steps outside this environment, as the continuity of care does not adequately track this journey. The only link is the treating physician who may see the patient outside the institutionalized health care environment.

Patient registers have been touted as the most logical tool to monitor the whole HT performance and the Australian Orthopaedic Association has to be commended on its efforts in establishing the

National Joint Replacement Registry. The Registry reports have provided early warnings of where a procedure, device or Health Technology may be failing, and they have ensured awareness and action by their professional bodies when required – albeit much later than optimally.

The TGA places responsibility for accountability of monitoring post-market performance onto all stakeholders, requiring reporting only at the worst extremes where a failure or near failure has occurred. The Sponsor/manufacturer is required to keep records, the fidelity of the data collected being set by the assigned risk level of the device. Unfortunately it is not possible to comment on how well this process operates as the public reporting is at a very low level. The AHIA expresses concern in regard to this issue as we can see the level of activity in similar overseas markets through the UK-MHRA- 99 device recall/alerts in 2010, US-FDA- 43 device recalls versus Aus-TGA – 1recall/4 alerts.

Recalls and alerts appear to be poorly maintained as assessed on the TGA Website.. Recalls and alerts show the ultimate failures of the system and should be reported as a major KPI. This was the case prior to 2009 but such reporting is now not as transparent.

The categorization of alerts and recalls creates differences in TGA processes which are not transparent and cause confusion. The differences between a consumer vs. hospital recall or a voluntary vs. mandatory recall are not clear.

All sponsors of Class IIb, III or AIMD devices are required to keep detailed product dossiers and report regularly on market performance. This would be a valuable source of information for re-imbursement reviews as referred to in Recommendation 14 of the HTA. However, this has not yet been implemented.

The AHIA would also highlight the issue of the cost implications where device failure occurs. As any warranty with surgical prostheses is usually negotiated at the hospital/sponsor interface, the liability that funds might choose to pursue with other stakeholders on behalf of their member is not always clear.

Reasonable people would agree that any cost implication for a patient arising from the failure of any device should not be borne by the patient.

**(e) the safety standards and approval processes for devices that are remanufactured for multiple use;**

The AHIA is unsure of the extent of re-manufacturing sponsors in Australia. We understand the rationale behind the development of this industry as most manufacturers do not want the liability and the increased risks associated with infection transfer or poor performance where devices are reused in a health care setting.

We are only aware of Ramsey hospital group which has partnered with Claveguard and Ascent Health Care Solutions (a Stryker Health Care company-US) which has FDA approved re-manufacture of two operating theatre consumables. We understand Ramsey is stock piling catheters awaiting TGA approval of the process for cardiac catheters. [1]

[1] http://www.ramsayhealth.com/news/documents/TRW_10_Christmas.pdf Page 11

Of consideration are the potential savings in reusing expensive technology weighted up against the potential costs. The trend to disposable health technology is a serious cost to the industry but this is not a simple issue to address, particularly as it also impacts on budgets and re-imbursement pathways.

Of particular concern to AHIA members is the growth of the Prostheses List to include devices which have the potential for re-use which is not adequately considered in setting reimbursement. Examples include external infusion pumps, external orthopaedic fixation frames etc.

The AHIA's general position is that the risks need to be clearly identified and the items grouped and accessed appropriately on the ARTG. As with all regulatory processes we should share with the European and American systems to ensure harmonization. The savings achieved would be motivating the market to pursue these processes and as in most other industries there are opportunities to recycle technology, which to a large extent should be encouraged and the benefits shared.

**(f) the processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices;**

TGA does have good reporting facilities for device incidents or failures and procedures but the requirement is only for ongoing education and awareness campaigns across the industry. Reporting is voluntary and website updates used to report on the source of reporting. This was dominated by sponsors with little user input, which is understandable considering the first steps in any corrective action by users would be taken at the clinical coalface. A concern, as mentioned earlier, is the Health Technology that escapes this controlled environment such as implantable prostheses. They may have diminished performance that impacts on the consumers Quality Adjusted Life Years, but with a low probability of being reported and only being captured when the patient presents for a revision.

This is separate from high revision rates which at first pass are not captured by the TGA unless reported. Interestingly, there are a number of MBS "revision codes" and it would be worth investigating if these can be reported as an early flag to an evolving problem.

As revision rates can be due to a number of issues: Surgical technique, Device Failure, Disease Progression, Hospital Interaction, Rehabilitation Process, etc. they are at first cut not a definitive answer re faulty devices. To contextualize all these inputs the close to ideal solution is a patient register such as the National Joint Research Register (NJRR). Refer Recommendation 15 of the HTA which as with Recommendations 13, 14, 15 have been deferred because they were considered not to be cost neutral. An interesting case study is the ASR Hip prostheses recently recalled by Johnston and Johnston which had shown high revision rates on the NJRR for the previous 3 years. Interestingly the ASR is not listed as an active recall on the TGA recall list which further heightens concerns relating to the transparency of the TGA processes.

The AHIA would also like to raise their member organisations as a potential source to report on and capture issues of HT performance as it impacts on the activity of their fund members.

This information should be publicly available for any Consumer to access. Whilst it may be considered relatively technical information, appropriate information can, of course, be devised, and

this would help to drive Consumer behaviours towards better performing Prostheses. Additional impact could be gained by ensuring any information about prosthesis performance is flagged and reported against industry pre-procedure information channels. The PL may be too late in the process, but a delay or hold being placed on re-imbursement for specific devices would quickly change consumption behaviours.

**(g) the effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified and the action taken once these devices are identified;**

The specific TGA recall and alert procedures, once triggered, are good. The problem is the lack of transparency as to the trigger for a recall or alert. A number of the technologies are imperfect and failures are anticipated. There should be established thresholds at which point alerts or recalls are triggered but at present this is not a transparent process.

The AHIA would recommend a flag on the ARTG public document notifying when a device is subject to an active recall as a means to improve transparency. Advice should also go to the relevant re-imbursement databases to allow them to instigate an active flag.

This lack of transparency creates concerns amongst AHIA members in ensuring the interests of their members are protected. Have all those fitted with ASR hips impacted by the recall been advised and do their clinicians have them under regular monitoring? What are the manufacturer's warranties provided and what are the regulatory demands on a voluntary as opposed to a mandatory recall?

The ASR problem highlights some special issues relevant to surgical prostheses in the fact that the surgeon has the ability to mix and match acetabular/femoral components from different manufacturers.

**(h) the effectiveness of the implemented recommendations of the Health Technology Assessment; and**

**The AHIA expresses concern that the processes relating to the PL have been changed based on input from the HTA Review even though the review highlighted the success of that process in achieving and maintaining a sustainable reimbursement model with high stakeholder engagement.**

Generally our specific comments set out in the table below are based on involvement with the Consultative Committee and the PLAC and by reference to the HTA website review of implementation status:

| Recommendation Number | Issue | Action To-Date | AHIA Comment |
|---|---|---|---|
| Recommendation 4c | Performance Reporting | MSAC – HTA Progress Website Show links to 2008-9 Annual Report | Documented outdated and issued before the HTA implementation. |
| | | TGA- Reported on HTA website as still in progress | |
| | | PLAC –HTA Website refers to PHI Bulletins | No KPI's indicated.<br>Phased implementation of 12b-e behind proposed schedule. |
| Recommendation 6f | Achieve HTA synergies through sharing | HTA Progress Website states recommendation will be achieved though secretariat heads meeting. | A strategy to identify and achieve synergies not evident. HTA expertise has been identified as a limited resource hence the need to share. |
| Recommendation 6g | Reporting on Performance Targets for HTA Reimbursement | PHI circulars on phase HTA implementation | Process targets developed or reported for re-imbursement systems. |
| Recommendation 7 | Concurrent Processes | Single Application and share information between agencies | Objective of increasing speed to market and simplifying application processes does not appear to have been achieved. |
| Recommendation 8 | TGA –Role, issues, rigour, protocols | Multiple Consultations | This recommendation goes to the heart of the senate enquiry involving increased rigor in regulator assessment & protocols for sharing information.<br><br>Concern that issues of communications was raised in inquiries as far back as 2004 with little improved performance evident. |
| Recommendation 9 | Strengthen and Streamline | Issue guidelines for sponsor application researched submissions | Actions aimed at streamlining processes to get more through put and reduce delays appear inadequate. New processes less streamlined than previous system and sponsors are reporting a significant frustration with the |

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| | | | system. Again there is a significant lack of transparency. Concern is they now have been given brief to review existing MBS items but not resourced accordingly. |
| Recommendation 10 | PLAC & Subcommittees Terms Of Reference | Reported in PHI bulletins as completed PHI82-10 | Reported as complete but the NOC and possibly the CAG's have not been given any new TOR. |
| Recommendation 11 | Restructure PDC | Reported in PHI bulletins as completed PHI82-10 | a. health economists – have been included but not effectively engaged in their TOR.<br>b. Balance of PDC or PLAC is further away from consumer and funds representation.<br>c. Independent Chair – John Horvath is not independent as employed as a consultant by the DoHA and is a previous employee. |
| Recommendation 12a | Continuous Applications | Reported in PHI bulletins as completed. PHI33-10 | Continuous applications are operating however they offer no perceived benefit (of reduced work peaks or improved speed to market) to sponsors or any other stakeholder as the Prostheses List is still generated twice per year. |
| Recommendation 12 b-e | Grouping and Benchmarking Benefits on the Prostheses List | Changed to a 3 Phased Implementation Program with Phase 1 reported as completed. | b. Grouping exercise is on technical rather that relative clinical effectiveness grounds.<br><br>c. Abolish negotiations and set benchmarks- Aug 2011 PL will have current and benchmarked benefits and the process will not be completed till Feb 2012 at best in a three phase program. Logic for removing negotiation as a benefit setting process was perceived lack of fairness and transparency yet it is still maintained as a benefit setting tool within the PBS.<br><br>d. Abolish maximum benefits – Major concern is that potential gaps will be invisible to the system as sponsors will be able to charge gaps |

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| | | | at any level. This new gapping process also impacts on other contractual legislation between hospitals and insurers.<br><br>e. new groups may be established for superior products- grounds for superiority are inconsistent, not transparent and of concern if not based on patient register performance. |
| Recommendation 13,14 & 15 | TGA & post market surveillance<br>Post market surveillance and re-imbursement linking.<br><br>High risk patient registers! | Reported by the TGA as subject to further consideration | We would strongly recommend that this recommendation along with 14 & 15 be effectively actioned.<br><br>Reported by the DoHA as delayed based on the cost implications. No cost benefit analysis flagged to allow the issue to progress. A number of the industry bodies including the AHIA have flagged a willingness to financially support their establishment. |

Yours sincerely

**HON DR MICHAEL ARMITAGE**
**CHIEF EXECUTIVE OFFICER**

12 August 2011