Medtronic
Alleviating Pain · Restoring Health · Extending Life

31st July 2008

Regulatory Burdens – Manufacturing & Distributive Trades
Productivity Commission
GPO BOX 1428
Canberra City, ACT 2601

Dear Sir / Madam,

Review of Regulatory Burdens on Business – Second Annual Review

About Medtronic and the Medical Technology Industry

- Medtronic is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world. With deep roots in the treatment of heart disease, Medtronic now provides a wide range of products and therapies.
- Medtronic Australasia is the leading supplier of advanced medical technologies in Australia and was established in 1973. Headquartered in Sydney we employ 350 personnel in Australia. In addition Medtronic manages a large distribution and agent network across Australia and New Zealand.
- Globally, every five seconds a person's life is saved or improved by a Medtronic product or therapy. In the two year period 2005-2007, 9,300 persons have received a Medtronic pacemaker or an implanted defibrillator.
- Medtronic's research efforts, strongly supported by Australian clinicians, result in new platform technologies. While Australia has been an early adopter of new medical technologies, not least related to the competency of its clinician skills, there is now a real threat to the continued early introduction of important new medical technologies. For some time, the vitality, quality and responsiveness of the private sector have distinguished it from public sector treatment, particularly for elective treatments. This has been an appealing factor for those with private health insurance. We see developing threats to the use of advanced medical technologies in the private sector and the current Prostheses Listing process contributes to that threat.
- Many of Medtronic's advanced medical technology products are listed on the Commonwealth Prostheses List; we are one of the largest sponsors of products. Approximately 95% of our items listed on the Prostheses List are products that fall into the higher risk classes assigned by the Therapeutic Goods Administration (TGA) - Class 11b, Class 111 or Class AIMD. That such a large proportion of our listings are higher risk class is an outcome of the success of Medtronic's mission to deliver important implanted and life-saving technologies.
- A well managed process in the Regulatory (Therapeutic Goods Authority) and Reimbursement (Medicare Services Advisory Committee and Prostheses List) are critical to Medtronic's ability to provide life-saving technologies to the Australian public. Unfortunately, we believe there are significant weaknesses with the current arrangements for both these processes. We also believe these could be readily addressed.

Observations on Medtronic Technologies and Their Value

- Medical technologies today are often characterized by extensive research and development (R&D) and comparatively quick product evolution (which is often iterative). Unlike the pharmaceutical environment, short patent protection life ensures that "me too" products follow quickly. In the 2006/2007 financial year more than 50% of Medtronic's Australian revenue was generated by products launched in the preceding 12 months.
- The medical technologies we develop and supply are sophisticated. Medtronic's intensive research and development program ensures continued product breakthroughs that benefit

clinicians and their patients. We invest approximately 12% of revenue in R&D to the benefit of clinicians and patients in Australia. The financial and human investments made by the company in R&D will continue to grow.

- We are committed to providing the necessary support to the clinician and the patient, for either the life of the device or the life of the patient.
- Training clinicians in the correct use of these medical technologies is vital to achieving optimal outcomes and maintaining important safety standards. In 2006-2007 Medtronic Australia provided more than 2,000 days of training and education for clinicians and key healthcare staff.
- Some implant technologies require the use of sophisticated instrumentation. Medtronic maintains an inventory of 9,000 items of loan equipment valued at more than $43 million for use by clinicians.
- Hospitals expect immediate availability of certain medical devices to be able to deal with both emergency and scheduled surgery. To do so hospitals employ consignment stocks from suppliers, which are paid for when and if used. For Medtronic this means that across Australia we allocate $75 million of consignment stock.
- Both 2e and 2f above represent major overhead costs that are a fundamental part of a responsive and effective health care system.
- Purchasers will often seek to separate out the cost elements associated with development, training, service support and consignment stock. In practice this is not always feasible and sometimes it can be a short-sighted approach. The optimal benefits of medical technology are only realized when first rate technology is supported by excellence in its use and on-going support.
- Medtronic considers there is already inequity in access to healthcare in Australia, notably between insured and uninsured (Public) patients. The current operation of the Prostheses List is widening that inequity by creating increasing numbers of gapped items for insured patients who may need to access a preferred technology recommended by their clinician.

Current Status of Affairs

Product Registration Regulatory Burdens - Therapeutic Goods Authority (TGA)

- Like medicines regulations, the regulation of medical devices requires significant reforms to improve the:
  - Timeliness, transparency and consistency of assessment and approval processes.
  - Consistency of decision making (with particular emphasis on the interpretation of legislation) and advice provided. For example there is a large discrepancy between advice provided by TGA Officers in regard to medical device variants.
  - Transparency between TGA decisions/assessments and industry
  - Fairness and equality in actions taken by the TGA that affect multiple medical device manufacturers/sponsors (especially in recall decisions)
- Timeframes for the processing of applications for registration of lower risk devices have become increasingly evident since the October 2007 transition cut-off date.
- Lack of transparency in the timing of why certain applications are assessed earlier than others for similar devices, which has resulted in an inconsistency in regards to assessment of higher risk devices, where there is no 'first come, first served, approach. Medtronic has experienced several incidences in which a device application made after another device application of the same class was assessed and approved significantly earlier. For example:
  - Medtronic Gemini (class III) submitted on 04/03/08 and approved on 22/07/08
  - Medtronic Detect (class III) submitted on 23/08/07 and as 31/07/08, remains in cue to be assigned to a TGA Officer.
- The inaccurate reporting on the efficiency of the TGA's medical device assessment branch as a result of the manner in which the TGA counts the number of working days taken to assess both higher and lower risk devices. That is, it appears that there is a tendency for the TGA to 'start the clock' from the date that a TGA officer is assigned to review an application. As demonstrated in the Medtronic Detect example detailed above, this may be as long as 12-months from the date of application lodgement with the TGA. Without a reform in this area, the usefulness of this tool appears to be devalued substantially.
- Inconsistency in the schedule of fees (especially with abridgements) charged by the TGA for higher risk devices. This creates a considerable amount of confusion for industry and adds to the

burden of registration costs. This inconsistency also detracts from the culture of fairness that the TGA is expected to function within.

- The lack of transparency between TGA and Industry in regards to the justification for increase in fees without TGA accountability and improvements to the assessment timeframes and process.
- Lack of accessibility of TGA officers who are assessing higher risk applications. This lack of open communication between TGA and industry effectively increases assessment times as application queries and misinterpretations are not able to be efficiently discussed.
- Lack of transparency in conveying new TGA application rules to industry. In particular, this applies to the use of particular GMDN codes. Recently, the TGA have governed that the use of 'unclassified' GMDN codes for all medical device applications will not be allowed. No official communication has been issued to industry to inform of this ruling.
- Lack of consistency with rulings relating to the use of GMDN codes. The TGA have always stated that they will use the GMDN codes generated by the GMDN code agency for applications submitted in Australia. However, the TGA does not appear to maintain its database of GMDN codes to be consistent with those listed on the GMDN agency database. This becomes a disadvantage for overseas manufacturers who are required by law to assign a GMDN code to products sold in Australia. They will typically use the GMDN agency database for this task but codes do not always translate well to the TGA GMDN database.
- Increasing number of occasions in which TGA Officers are dictating the content of medical device applications submitted by Australian sponsors. This particularly relates to Intended Purposes that lawfully can only be determined by the manufacturer. This creates confusion for Australian sponsors who are attempting to comply with both Australian medical device legislation and with the mandates of the TGA.
- Concern regarding the monopoly the TGA has in regarding to the approval of medical devices containing components of animal origin or that contain substances classed as medicines. These applications are expensive and lengthy (approximately 18 months) and delay the entry of medical technology that may have already been assessed and approved by international notified bodies

Recommendations

1. The TGA and industry would be better served if the 'clock' for determining the number of working days taken to assess high & low class devices, is started from when payment is received by the TGA.

2. Consistency in fees charged by the TGA and transparency of increases of fees and subsequent improvements to the assessment process.

3. Improve access to TGA officers to facilitate open communication with Sponsors to minimise delays in the assessment of medical devices.

Reimbursement Regulatory Burdens – Medical Services Advisory Committee (MSAC)

- Assessment of new medical procedures, involving medical devices, by MSAC continues to lack transparency and a sense of urgency, where in Medtronic's experience it is not uncommon for a review to take over 2-years.
- The inefficiencies in the requirement to re-submit a completely new application in the event that the Minister endorses a negative MSAC recommendation. It would be more efficient if there was a re-submission process setup that did not require a new application and the subsequent time frame associated but rather an application process linking to the review conducted by MSAC previously. This will negate the requirement to commence an application and review from the beginning and minimise the duplication in the process.

Recommendations:

4. Removing the requirement where applicants are required to submit a new application in order to provide additional/new information in support of a previous MSAC review that resulted in a negative recommendation.

5. Decrease the current review process timeframe to allow a timely assessment of services associated with new medical devices and the facilitation of access to life saving new technologies.

Reimbursement Regulatory Burdens – Prostheses List

- Medtronic's submission to the Doyle Review is provided to the Productivity Commission for the details of the Prostheses List issues (Attachment 1)
- Robert Doyle stated in his report dated October 2007:
  "In delivering his findings into the Review of the Prostheses List Arrangements in October 2007, Mr. Robert Doyle stated: 'It is in some respects unfortunate that the Act required a review of the new process after such a period of operation. However, it is already clear that some elements of the current arrangements are unsustainable or inefficient, and I have identified a number of recommendations to improve the operation of the listing process while retaining the fundamental principles of payments for clinical effectiveness and cost effectiveness. The recommendations generally will result in a streamlined listing process and reduced administrative burden and red tape."
- However, despite the findings of this review the Doyle recommendations provided in his report, that would provide significant improvements to the Prostheses List arrangements, this report remains outstanding with the Minister of Health & Ageing who is yet to deliver a response to this report.
- The HTA review recommended in the Banks Report dated January 2006 remains outstanding - Recommendation 4.22
  The Australian Government should undertake a system-wide, independent and public review of health technology assessment, with the objective of reducing fragmentation, duplication and unnecessary complexity, which can delay introduction of beneficial new medical technologies. Health technology assessment processes and decisions should also be made more transparent, in line with good regulatory practice.
- Significant issues remain to be experienced in the lack of transparency and process of the Prostheses List arrangements and these can be evident by the 7 Internal Review Applications into specific process issues requested by Medtronic of the Prostheses Section. TO date, Medtronic has received a response to 3 of these reviews, in which all three determined 'deviations from the process'

Recommendations:

6. Doyle Report into the Review of Prostheses List Arrangements (October 2007) Action on the recommendations of the Doyle Report dated October 2007 not be any further delayed. Of particular reference are those Doyle recommendations that are relevant to the activities of the Productivity Commission as part of this annual review of regulatory burdens on business are recommendation numbers 1, 2, 5 & 10(Refer to Appendix 1).

In conclusion, there continues to be lengthy delays in introducing life saving technologies to Australian patients due to regulatory requirements, procedural review of MSAC and reimbursement examination for the Prostheses List despite various recommendations for improvement provided by such reviews as those by Banks 2006 & Doyle 2007. There is a need for a streamlined, transparent and accountable process for the registration, assessment and reimbursement of new medical technologies. Therefore, Medtronic recommends the parallel review of medical devices for regulatory approval by the TGA, review by MSAC for the service associated with a medical device and review of the medical device for listing on to the Prostheses List which would result in a more streamlined process and supports the timely access to life saving technologies for Australian patients.

Regards,
Medtronic Australasia Pty Ltd

Appendix 1 – Doyle Report Recommendations 1, 2, 5 & 10

1. The Prostheses List be issued three times a year in April, August and December, including all items that have completed the application or review process at least four weeks before the date of effect of the List.
2. The requirement for an ARTG number prior to applying for listing be removed, and sponsors allowed to apply concurrently for an ARTG number and inclusion on the Prostheses List.
5. As the review in recommendation 4 is completed for each group, the current practice of annual review of all items be replaced by a process of review by exception initiated by a sponsor, insurer, or the Prostheses Committee. A review cannot be instigated less than twelve months after initial listing, or twenty-four months after the last review, and any request for review must be supported by appropriate evidence.
10. The following process for considering applications be adopted:
    - Sponsors applying for a new listing must nominate a comparator item and an associated MBS item.
    - If the Prostheses Committee accepts that the comparator and the MBS item is appropriate, and the sponsor wishes to accept the same benefit level as the comparator, the Committee will recommend to the Minister listing at that benefit level. (If the Committee does not accept the comparator, it must suggest another.)
    - If the sponsor wishes to apply for an increased benefit relative to the comparator, it must provide clinical evidence of improved effectiveness and of cost effectiveness at the proposed benefit. Evidence of effectiveness should be at a minimum case series data.
    - If evidence of improved effectiveness is not available, the item will be recommended to the Minister for listing at the comparator benefit for twelve months to allow data to be collected, and may then be submitted for review.
    - Applications for increased benefits for a new item or a review of existing benefits will be considered by a relevant Clinical Committee of the Prostheses Committee, which will make a report to the sponsor including the recommended benefit level, the comparator used, and other relevant information.
    - If the sponsor does not accept the recommendation, the matter will be considered by a member of the panel of arbiters who will hold a discussion with the sponsor and a designated representative of the Prostheses Committee. The arbiter's finding on the benefit level will be recommended by the Prostheses Committee to the Minister.

2nd August, 2007

The Prostheses Review Secretariat
Department of Health and Ageing
MDP 19
GPO Box 9848
CANBERRA ACT 2601

Dear Sir or Madam,

Medtronic Submission to Prostheses Parliamentary Review

Please find attached my company's submission to the Prostheses Parliamentary Review.

I would appreciate acknowledgement of this submission.

Yours sincerely,

James H. Stanistreet
Managing Director
Medtronic Australasia Pty. Ltd.

Enclosure: Medtronic Submission

1. Why we are lodging this submission:

a. Medtronic is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world. With deep roots in the treatment of heart disease, Medtronic now provides a wide range of products and therapies.

b. Medtronic Australasia is the leading supplier of advanced medical technologies in Australia and was established in 1973. Headquartered in Sydney we employ 350 personnel in Australia. In addition Medtronic manages a large distribution and agent network across Australia and New Zealand.

c. Globally, every five seconds a person's life is saved or improved by a Medtronic product or therapy. In the last two years 9,300 persons have received a Medtronic pacemaker or an implanted defibrillator.

d. Medtronic's research efforts, strongly supported by Australian clinicians, result in new platform technologies. While Australia has been an early adopter of new medical technologies, not least related to the competency of its clinician skills, there is now a real threat to the continued early introduction of important new medical technologies. For some time, the vitality, quality and responsiveness of the private sector have distinguished it from public sector treatment, particularly for elective treatments. This has been an appealing factor for those with private health insurance. We see developing threats to the use of advanced medical technologies in the private sector and the current Prostheses Listing process contributes to that threat.

e. Many of Medtronic's advanced medical technology products are listed on the Commonwealth Prostheses List; we are one of the largest sponsors of products. Of the 546 Listings we hold, 535 of these are products that fall into the higher risk classes assigned by the Therapeutic Goods Administration (TGA) - Class 11b, Class 111 or Class AIMD. That such a large proportion of our listings are higher risk class is an outcome of the success of Medtronic's mission to deliver important implanted and life-saving technologies.

f. A well managed Prostheses List is critical to Medtronic's ability to provide life-saving technologies to the Australian public. Unfortunately, we believe there are significant weaknesses with the current arrangements. We also believe these could be readily addressed.

2. Some brief observations on our medical technologies and their value:

a. Medical technologies today are often characterized by extensive research and development (R&D) and comparatively quick product evolution (which is often iterative). Unlike the pharmaceutical environment, short patent protection life ensures that "me too" products follow quickly. In the 2006/2007 financial year more than 50% of Medtronic's Australian revenue was generated by products launched in the preceding 12 months.

b. The medical technologies we develop and supply are sophisticated. Medtronic's intensive research and development program ensures continued product breakthroughs that benefit clinicians and their patients. We invest approximately 12% of revenue in R&D to the benefit of clinicians and patients in Australia. The financial and human investments made by the company in R&D will continue to grow.

c. We are committed to providing the necessary support to the clinician and the patient, for either the life of the device or the life of the patient.

d. Training clinicians in the correct use of these medical technologies is vital to achieving optimal outcomes and maintaining important safety standards. In 2006-2007 Medtronic Australia provided more than 2,000 days of training and education for clinicians and key healthcare staff.

e. Some implant technologies require the use of sophisticated instrumentation. Medtronic maintains an inventory of 9,000 items of loan equipment valued at more than $43 million for use by clinicians.

f. Hospitals expect immediate availability of certain medical devices to be able to deal with both emergency and scheduled surgery. To do so hospitals employ consignment stocks from suppliers, which are paid for when and if used. For Medtronic this means that across Australia we allocate $75 million of consignment stock.

g. Both 2e. and 2f. above represent major overhead costs that are a fundamental part of a responsive and effective health care system.

h. Purchasers will often seek to separate out the cost elements associated with development, training, service support and consignment stock. In practice this is not always feasible and sometimes it can be a short-sighted approach. The optimal benefits of medical technology are only realized when first rate technology is supported by excellence in its use and on-going support.

i. Medtronic considers there is already inequity in access to healthcare in Australia, notably between insured and uninsured (Public) patients. The current operation of the Prostheses List is widening that inequity by creating increasing numbers of gapped items for insured patients who may need to access a preferred technology recommended by their clinician.

3. Our understanding of the Government's purpose in reforming the Prostheses List and now undertaking this Parliamentary Review

a. We understand that the Government introduced the changes to the Prostheses List management in 2005 for the purposes of:

i. Enhancing the value of health insurance and increasing choice for consumers[1]
ii. Achieving cost containment of health insurance premiums by reducing one of the drivers of premiums (prostheses)[2]
iii. Improving administrative arrangements which were considered complex. (Ibid)

b. We understand that the Government's approach in its review of prostheses funding was influenced by the way in which pharmaceutical products are recommended for PBS funding by the Pharmaceutical Benefits Advisory Committee (PBAC).

c. During the Public discussion and the Senate Enquiry in 2004/2005, concern was expressed that the Bill and the introduction of gap payments might, amongst other things, limit choice, reduce access to newer technologies and by so doing, make private health insurance less attractive. The 2005 Amendments provided for this Parliamentary Review with a view to gauging the impact on patients of the reforms. The Terms of Reference (TOR) list five specific areas for review.

d. This submission addresses the TOR in order, commencing with: **TOR 1: "Assess the effectiveness of the arrangements …"**

4. TOR 1: a. "ensuring insured persons' affordable access to safe and clinically effective prostheses …"

Contain insurance premium increases:

[1] The Hon Trish Worth, MP. Hansard, National Health Amendment (Prostheses) Bill 2004, Second Reading 12th August 2004.
[2] Dr. Andrew Southcott, MP, Hansard, National Health Amendment (Prostheses) Bill 2004, Second Reading 14th February 2005.

a. Medtronic understands that the rate of growth in expenditure for prostheses, as measured by the Private Health Insurance Administrative Council (PHIAC) has slowed from the 29% recorded for the two year period 01/02 to 03/04, to 7.9% in FY 05/06. Thus the Government's intention to provide affordable access to prostheses can be said generally to have been met, although there are concerns with timely patient access to important new medical technologies.

b. In presenting the Prostheses Bill to the Parliament in 2004, Minister Abbott noted that the Bill would "*allow health funds to continue to benefit from the stronger negotiating power of the public hospital network*" and "*the revised bill now recognizes that public hospitals may be able to purchase prostheses at prices that are below the benefit amount or minimum benefit amount.*" [3]

Recommendation:

The Parliamentary Review should note that while the reforms have served to slow the rate of growth of prostheses benefits paid by health insurers, they have also slowed the rate of introduction of new technologies. There is a likelihood that "homogenization" of technologies will occur, potentially eliminating one of the significant benefits of private health insurance.

5. *Frequency of Listing:*

a. The current arrangement for allowing products to be added to the Prostheses List only twice each year has slowed our efforts to bring important new products to patients. Even with sound planning for regulatory approval it is easy for new technologies to "miss" the List, in which case delays of up to a year can occur. At Appendix 1 to this submission we have listed some examples where TGA approval has been obtained but the process of Listing has been delayed.

b. Medtronic supported the industry view that listing for new items occur twice yearly until the new arrangements were embedded. As that has now occurred there should be an immediate move to quarterly listing, with an expressed aim of shifting to "real time" listing within 12 months.

Recommendation:

In order that new technologies reach patients in a timely manner, increase the frequency of listing new products to quarterly. Plan to move to "real-time" listing within 12 months.

6. *Review of Current Listings:*

a. It was understood from the outset that the review process would be a major undertaking.

b. The timings and workload for the annual reviews cannot be comfortably managed by any of the parties. There has been demand for suppliers to meet increased workloads and turnaround times. Furthermore, the review times by the PDNG and CAG's are too slow, consequently placing even tighter deadlines on suppliers to complete negotiations prior to the release of the Prostheses List for all items that have not had a benefit review in 12 months. The opportunity to negotiate has been eroded to the point of process failure. Some specific examples have been included in Appendix 1.

c. Adequate time needs to be allocated for fair negotiations to occur.

d. It is administratively burdensome to review benefits for in excess of 9,000 items each year and it appears to be a waste of resources. On the evidence of outcomes from the last 8,877

[3] The Hon Tony Abbott, MP. Hansard, National Health Amendment (Prostheses) Bill 2004, Second Reading 1 December 2004.

products reviewed in July 2007 - 87% of those products retained the current minimum benefit[4], 6% received an increased minimum benefit and 7% faced a reduced minimum benefit – this is clearly an ineffective and time-wasting process. Items not reviewed could be addressed by a simple indexation increase. This would allow effort to be better applied to focusing on new items for listing and reviewing existing items by exception. This step would free up resources to be able to better manage new listings.

e. Many older technologies are rightly retained on the List; however, caution needs to be applied in use of these as comparators to new technologies.

f. Better focussing of the review effort will release resources for all parties. This will lead to better submissions, improved evaluations and create the opportunity for improved transparency, which currently suffers as a result of the very large workload.

Recommendations:

1) Cease the full review of the List and review existing items only by exception. Limit the number of "exceptions" to say, no more than 15% of existing items with a supplier or a health insurer able to request an "exceptional review".
2) Ensure that older technology items which remain on the List are not inappropriately used as comparators.
3) Apply an annual CPI-related increase to those existing items not reviewed.

7. TOR 1: b. "limiting inappropriate pressure on health insurance premiums …"

We have no comments, however, we are interested to learn of the PHI Ombudsman view of any consumer concerns around the growing number of gap payments and the impact of these on the attractiveness of private health insurance.

8. TOR 1: c. "Delivering consistent, fair and transparent insurance benefits for prostheses"

a. While this question may be intended primarily to examine outcomes for insurance contributors, it also provides an opportunity to make observations about a lack of consistency, fairness and transparency for suppliers generally.

b. It is of concern that the process guiding the management of the Prostheses List has lacked adequate guidance and transparency for the two years that the arrangements have been operating. Medtronic notes the release of PDC Attachment A: "***Prostheses and Devices Negotiating Group Governance Arrangements/Operating Procedures***" dated 26 June 2007, and released after the TOR for this Review. While this recently released guidance will require time and practice to fully evaluate; we have included in Appendix 2 to this Submission, some early observations on those aspects of the guidance which appear to require further review. These comments are based upon our experience of the past two years.

c. For the past two years the negotiation process has lacked fairness, transparency and goodwill. Procedural fairness and due process issues are critical as when mishandled, they can lead to significant commercial disadvantage. There needs to be:

i. transparency of identified comparators before negotiation commences,
ii. a clear indication that clinical data provided has been subjected to clinical examination and the recommendation is relayed back to sponsors,

[4] Note that while 87% of the products did not have a benefit change, they were the subject of extensive benefit negotiation. This is an extensive workload.

iii. effective communications from PDNG and Prostheses Coordinators wherein suppliers' correspondence is answered in a timely manner with due regard to an ordered procedure (especially where there is a deviation from process), and
iv. adequate time allocated for fair negotiations to occur.

9. *Transparency:*

a. The Prostheses Listing arrangements over the past two years have been characterised by a remarkable and unacceptable lack of transparency. Unlike the PBS process where the deliberations of the PBAC are documented and available for public scrutiny, the prostheses listing arrangements have been shrouded in secrecy.

b. Without suggesting that DoHA apply parallel processes for prostheses and pharmaceuticals, there is considerable scope to bring to the Prostheses List management the experience with transparency that DoHA has from its management of the PBAC/PBS processes.

c. Medtronic does not support claims that Commercial-in-Confidence classifications inhibit transparency.

d. As noted in paragraph 4 above "Review of Current Listings" the extensive and wasteful effort applied to reviewing approximately 9,000 items each year limits the ability to do some of the important things that need to be done, such as documenting processes and outcomes, and delivering important transparency.

Recommendations:

1) The Prostheses List should receive an equal level of transparency to that applied to the PBS.

2) In the PDNG and the CAG processes there must be full disclosure and documentation of outcomes. This must include:

i. all comparator products,
ii. reason for selection of the comparators
iii. features identified with comparators
iv. utilisation figures (which have not been revealed for the past two years) must be made available during negotiations, and
v. publishing meeting minutes

10. *Fairness:*

a. We are concerned about the independence and impartiality of the Prostheses and Devices Negotiating Group (PDNG). Currently the PDNG is appointed by the PDC on individual recommendations made by the AHIA. Members of the PDNG are largely current or former staff of health insurance companies. AHIA pays $1.5 million annually for the operations of the PDNG, although we note this is not mandated in the same way as suppliers are mandated by legislation to meet the annual costs of $2.5 million for the funding of the prostheses arrangements.

b. We hold strongly to the view that the PDNG not only be independent, but that it is seen to be impartial. When the Government introduced the revised legislation to the Parliament in December 2004, the Shadow Health Minister noted: "It was clear to all in the health sector that these initiatives were being driven by the Australian Health Insurance Association, which certainly has access to the government's ear when it comes to matters of health policy".[5] Whether or not this is true, the role

[5] Ms Julia Gillard, MP. Hansard 14th February 2005. National Health Amendment (Prostheses) Bill 2004 Second Reading.

played by AHIA in nomination of PDNG members and the subsequent operation of the PDNG is not acceptable to our industry sector.

c. The qualifications of members of the PDNG should be related to the important therapeutic judgment role they fulfill. The required skills sets should be made clear. Suppliers should recommend 50% of the appointments to the PDNG and in return be expected to meet 50% of the costs of operation of the group.

d. Deliberations of the PDNG are often delayed due to the need to refer questions to the CAG. A CAG member should attend all PDNG meetings to reduce unnecessary delays. Without suggesting the role of the CAG be usurped, it would be beneficial for more members of the PDNG to hold clinical qualifications.

e. We have experienced both CAG and PDNG commenting upon safety and efficacy of products. We hold strongly to the position that Government has assigned the assessment of these matters to the TGA. Once a product has been Included on the ARTG, there should be no further discussion of safety and efficacy allowed in the process of achieving a Prostheses Listing and determining a benefit level.

f. Transparency around the membership of the CAGs and PoCE is warranted. There needs to be confidence in the qualifications and experience of those appointed to review specific therapies. As we experienced with our Internal Review application with Stretch Coil EXTENSIONS, this is not always the case.[6]

g. We have noted in the preceding discussion of ***Fairness***, that the proceedings of both CAG and PDNG must be documented.

Recommendations:

1) *The selection and operation of the CAG and particularly the PDNG must be seen to be impartial and the deliberations of these committees documented and available for public scrutiny.*
2) *CAG and PDNG members must disclose any conflict of interest.*
3) *Suppliers must be able to request a formal review process where they believe that either process or decision taking is flawed.*
4) *A non-voting CAG member should attend PDNG negotiations.*
5) *The membership of the PDNG should be examined with a view to increasing the clinical qualifications within the group.*
6) *Suppliers should nominate 50% of the membership to the PDC and in return meet 50% of the costs of operation of the PDNG.*
7) *Clear timeframes for processes and responses need to be established, documented and observed.*
8) *Improve the guidance from the PDC such that PDC sets the direction and objectives for the PDNG and to a lesser extent, the CAGs.*
9) *Achieve transparency in PDNG processes and not allow these to be obfuscated by claims of "Commercial in Confidence" considerations.*

11. *Gap Payments:*

a. The government's intent that Gaps be visible is occurring. There has been a dramatic increase in the number of prostheses attracting gap payments; with more than 8% of items now carrying gap payments. Where Medtronic products carry a gap, we have not yet sought payment of a gap lest patient access to important technology be threatened.

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[6] DoHA advised Medtronic on 9th July 2007: *'The clinicians on the PoCE have expertise in relation to specific technologies and procedures and are well placed to review literature and clinical evidence put forward by the sponsor to determine clinical effectiveness and relative clinical effectiveness of their product. The clinicians conducting the clinical assessment of new products are chosen for their expertise in the field. There is no expectation that the clinicians will have specific experience with every technology in their field'*

b. This position has been vindicated as we have noted some hospitals have advised suppliers to remove from their premises any stock of gap permitted items.

c. While we have been able to carry gaps thus far, this is not sustainable without having a significant adverse effect on the introduction of important new technologies. Recently, we have commenced gap recoveries.

Recommendations:

1) Evaluate the impact of gaps where hospitals choose to not stock gapped items, effectively denying certain technologies to patients.

2) Note that the increasing number of gaps may act to make private health insurance less attractive to consumers.

12. *Consistency:*

a. Consistency is judged to be poor for three primary reasons:

i. The lack of transparency where no public records are maintained.
ii. The lack of published guidelines - until just recently.
iii. The uncertainty around comparators used and reference to clinical advice.

b. Adoption of transparent processes may be expected to substantially improve consistency in practice and decision making.

13. TOR 1: d. "ensuring the efficiency and sustainability of the administrative process and minimizing administrative costs for all relevant parties"

a. The current process has significantly added to our costs.

b. Across all suppliers we understand the current direct recoverable costs to be $2.5 million. To these must be added the additional costs borne by companies to manage the processes. In the case of Medtronic these are:

i. Medtronic resource commitment increased by 50% over the last twelve months to deal with the 546 products included on the July 2007 Prostheses List
ii. The Prostheses reforms have required employees to be up-skilled, resulting in more expensive employees.
iii. The financial impact of the direct fees and the additional administrative burden to Medtronic is difficult to accurately quantify, but is thought to be in the order of $500,000+ annually.

Recommendation:

There needs to be a broader view of the costs of administering the Prostheses List. Judgements should not merely be restricted to reviewing annual variations in prostheses expenditure by health insurers, but rather be cognizant that the inefficiencies of the current arrangements generate a range of costs that must be met.

14. TOR 2: "Assess the adequacy of informed financial consent arrangements for prostheses particularly where a gap is payable by insured persons"

We have no comments.

15. TOR 3: "examine the extent of out-of-pocket costs experienced by insured persons for clinically appropriate prostheses"

We have no comments.

16. TOR 4: "recommend measures …"

With each of our observations we have made recommendations for improvements to process. Additionally, at Appendix 3 we have recommended an "improved model".

17. TOR 5. "Human Tissue Products"

We have no comments.

18. Conclusion:

In this submission we have highlighted a series of weaknesses in process and transparency that are features of the current scheme. Collectively, those weaknesses work against creating timely and affordable access to advanced medical technologies. We have illustrated where unfair and unrealistic barriers, and unacceptably slow time-frames, impede the path to reimbursement. We have confirmed that the public sector can acquire new technologies ahead of the privately insured sector.

Should these issues not be addressed and rectified, then over time they will become disincentives to the early introduction of new technologies, something that has enabled the Australian healthcare system and the private sector in particular to thrive. Companies will have a declining interest in the provision of advanced technologies where a gradual "homogenization" of device types is occurring.

There is the likelihood of a wider malaise, extending beyond immediate treatments and into research and development. There will be harmful effect on Australia's reputation for delivery of a high quality healthcare system featuring a successful complementary mix of public and private hospitalisation.

The above conditions will contribute to rising frustrations for the insured population as they become more aware of the limitations on choice and the widening gaps; they may be expected to strongly question the value of their health insurance product.

We have also conceded that the initiative has recorded some success in achieving what it set out to do: limit the rate of growth of health insurance premiums by containing prostheses expenditure.

We have expressed a view that the current arrangements could be improved with some relatively simple and reasonable steps, such things as bringing more transparency and rigor to the process. Most of those things we have suggested be adopted would be consistent with well established practices in the BPAC/PBS environment applied for pharmaceuticals. Moreover, the recommended changes would be consistent with Government's approach to transparency and fairness in its dealings with business.

Against most of the points within the TOR for the Review we have made recommendations. We urge that you carefully consider adoption of these recommendations; they do not recommend significant change but can be seen as "tweaking" the current process.

Importantly, we have pointed out that much of the current work is non-productive. A reallocation of resources away from this non-productive work will release assets that can be applied to make major improvements to process and transparency.

We consider adoption of these changes will do much to restore reasonableness and confidence in a process that can bring timely and affordable access to important advanced technologies in the private healthcare environment.

Medtronic stresses its continuing commitment to collaborate and communicate with Government to achieve the aims established for delivery of high quality healthcare.

Appendix 1 – Timings:

The effective dates of the MSAC recommendations are currently not aligned with the effective dates of the Prostheses List. As a result, there is a limiting effect for surgeons to offer breakthrough technology to the Australian public.

> A specific example of this was the removal of cervical discs from the August 2006 Prostheses List, following an MSAC recommendation that concluded there was an "absence of evidence of effectiveness". We were advised of this decision approximately five weeks prior to the effective date of the August 2006 Prostheses List (which was the same time that the cervical disc rebate codes would cease to exist). No interim MBS procedure funding was made available, leaving surgeons and patients with the only option of fusion at very short notice.

Some specific examples to illustrate the point we make at paragraph 5a are:

i. For the August 06 List, the PDNG provided Medtronic with 6 working days to respond to 1st round offers made on SPCAG items, of which 188 items were being negotiated (August 06 PL).

ii. For the review of grandfathered items for the August 06 List, we were given a 25 working day turn-around to provide data for each of our then 445 billing codes.

iii. For the recent June 2007 benefit review of Spine items, Medtronic received 4th round offers at 5.02pm on 24/4/07. The deadline for a response was 12pm Thursday 26th April 2007; therefore the turnaround response time was only a matter of working hours, as the 25th April 2007 was a public holiday. This is by no means an exceptional case.

There is evidence that ARTG cut-off dates for Prostheses List submissions are impeding technology reaching privately insured patients, whereas pubic patients face no additional delays after ARTG approval. This must surely be an unintended outcome as it works against the attractiveness of private health insurance.

The recently released guidance by DoHA[7] has not addressed the concerning issues around timeframes.

[7] Attachment A PDNG Governance Arrangements/Operating Procedures

Appendix 2: PDNG Procedures

PDC

Prostheses and Devices Committee

Prostheses and Devices Negotiating Group

Governance Arrangements/Operating Procedures

The Prostheses and Devices Negotiating Group (PDNG)

1. The PDNG are directly accountable and provide advice to the Prostheses and Devices Committee (PDC). Between meetings, the PDC Chair and the Prostheses Secretariat may provide guidance to the PDNG. ***Sponsor should have transparency of the advice being provided to the PDC, and should be given a copy of all meeting minutes.***
2. On behalf of the PDC the PDNG negotiates benefit amounts with the sponsors of products recommended by the PDC for listing on the Prostheses List. They also renegotiate benefit amounts for listed prostheses as directed by the PDC. ***See our comments regarding frequency of reviews in our submission.***
3. Currently the PDNG is funded by the Australian Health Insurance Association (AHIA). The PDNG operates as a unit with full time staff, an independent email system and has the facility to conduct meetings and store commercially sensitive data. ***The weighting given to AHIA nominations needs to be addressed.***

Membership

4. Members of the PDNG are appointed by the PDC currently by way of nominations from the AHIA. If there is a shortfall from the AHIA, members can also be nominated by the Australian Private Hospital Association (APHA) or Catholic Health Australia (CHA). ***See comments in our submission; there needs to be more independence and clinical knowledge within the PDNG .***
5. The members of the PDNG are required to sign Deeds of Confidentiality and declare any conflicts of interest before being provided with any data from sponsors, clinicians or the PDC Secretariat.
6. Currently there is a facilitator (Departmental Advisor) who provides advice to the PDNG on policy and due process in relation to negotiations.

Communication

7. The PDNG are to meet on a regular basis with the Chair of the PDC and Directors of the Prostheses Section (Department of Health and Ageing). One or two PDC Members may also attend these meetings. ***Meeting minutes should be provided to the sponsor.***

8. The purpose of these meetings is for the PDNG to:
    - Receive direction from the PDC;
    - provide feedback to the PDC on relevant negotiation issues including advice on any issues causing concerns to sponsors; and
    - Consider likely impacts on proposed benefit amounts eg mandatory cost recovery, CPI etc.
9. The PDNG communicate directly with sponsors. Procedures are available for PDNG staff to minimise breaches of security. If a breach does occur the breach and subsequent corrective action are to be reported to the PDC. ***We are unsure which breaches are intended. We have experienced our confidential data being wrongly transmitted to another supplier.***
10. All communications from stakeholders should be conducted through the Secretariat.
11. Sponsors will be made aware by the Secretariat of their clinical sub-group and any regrouping before negotiations commence, including the allocation of any suffixes. Where clinical regrouping occurs across an entire sub-group, sponsors are to receive a revised copy of the complete sub-group, prior to negotiations. ***If the re-grouping is proven to be incorrect, then negotiations should immediately cease for those items.***

Conduct of negotiation ***Throughout this point independence of the negotiators and transparency are vital.***

12. The negotiation process will occur in accordance with policy guidance. ***What guidance and who is policing this?***
13. The PDNG will offer an appropriate benefit in accordance with this guidance. ***"Appropriate" is a vague term. There needs to be a means of escalation and appeal.***
14. Negotiations will be conducted honestly – this is a mutual responsibility. ***Comparators must be disclosed to suppliers.***
15. The PDNG will deal equally with all sponsors.
16. Benefit offers will not be misrepresented ie negotiators will not make offers which are not made on the basis of allowable factors and claim otherwise.
17. When requested, the PDNG will provide utilisation data to sponsors in respect of the sponsor's own devices – in return, sponsors should provide their utilisation data to the PDNG in order to minimize disagreements.
18. Although not to be used as a benchmark, where the PDNG considers public hospital pricing, the source and currency of the data will be shared with the relevant sponsor. ***Why is public hospital pricing being considered at all if it is not to be used as a benchmark?*** The PDC Secretariat will provide sponsors and the PDNG with any new clinical guidance provided by CAG or PoCE that may impact on the sponsor's device and provide sponsors with an opportunity to respond through the negotiation process. ***A supplier response should be referred back to the CAG.***

19. The PDNG is to provide reasons for reductions in proposed benefits. Reasons provided must rely on factors identified in the basis for benefit offers and be consistent with policy guidance but should not breach commercial-in-confidence.

Benefit Proposals

20. Initial benefit proposals from the PDNG are developed having regard to:

- the information they have available to them, including information provided by the sponsor such as technical support, warranty, provision of consignment stock, freight, loan set kits etc;
- current benefit amount/s;
- benefit amounts for similar products already on the Prostheses List;
- sponsor proposed benefit amount;
- clinical advice from the appropriate CAG or the PoCE - this clinical advice is to be provided to the PDNG and the sponsor;
- utilisation data; and
- additional features as reflected by the CAG allocation of a suffix.

21. Initial benefit proposals should not vary by more than ± 10% of current benefit amount unless an error has been made, advice has been provided by a CAG or PoCE member and agreement endorsed by the PDC. ***We had 80% reductions in benefit on some items in the last round of negotiations and that directly results from a lack of transparency around process.***

22. The PDNG is to provide reasons for their initial offer. In many cases the reasons may have a common theme eg to align with other products in the group/sub-group.

23. Sponsors should treat the initial proposal as the start of the benefit negotiation. They are at liberty to respond with a counter-offer.

24. At this point sponsors have an opportunity to meet with the PDNG, either face-to-face or via teleconference, to go through each item where further details can be provided by both the PDNG and the sponsors. The negotiation process may require more than one meeting. The only limitation on the number of meetings possible being the timeframe required to produce the Prostheses List.

25. To enable meaningful discussions, meetings should be sought after the sponsor makes a counter proposal to the PDNG initial proposal. Sponsors and/or the PDNG can ask for a member of the PDC Secretariat to be present during a benefit negotiation meeting to advise on policy and procedures.

26. Sponsors have a period of 10 working days to respond to the initial offer (accept or make a counter proposal) and a period of 5 working days for subsequent offers. This period may be shortened with the agreement of the sponsor.

27. Where the sponsor does not respond, the PDNG will when presenting its report will use the benefit proposed by the sponsor in its application as the maximum benefit and the PDNG proposal as the minimum benefit (these may be the same in some instances).

28. For CAG products, the material sent by the PDNG will include advice on the group/sub group recommended by the CAG. Where the CAG has recommended a group/subgroup different to that proposed by the sponsor, the PDC Secretariat will advise the sponsor, and the PDNG prior to benefit negotiation.

Clinical information

29. The PDNG is not tasked to assess the clinical aspects of a product. Any submission based on the clinical effectiveness of a product put forward during benefit negotiation will be referred to the CAG or PoCE for assessment and advice to the PDC for it to consider along with the PDNG report. ***CAG advice to the PDC needs to be documented and suppliers should be provided with this, as well as the PDNG report.***

30. The preference is for clinical information to be provided early in the cycle to allow consideration by clinicians prior to benefit negotiations commencing. ***Our experience is that the clinical information provided early in the cycle is not reviewed in detail and we end up having to re-send clinical information again and again to differentiate the item.***

Recommendation to PDC/Minister

31. The PDNG will be expected to negotiate a benefit level that reflects the most appropriate benefit but at the same time ensures supply of the product. ***Clinical choice is adversely impacted when hospitals ask suppliers to remove gap items from consignment.***

32. The PDNG will need to take into account the aim to have at least one clinically effective no gap prosthesis for every in-hospital procedure where a prosthesis is required and where there is an associated Medicare Benefit Schedule (MBS) number.

33. Should a sponsor and the PDNG not be able to agree on a benefit amount, the PDNG will recommend to the PDC listing on the prostheses schedule with a gap. The benefit amount for the group will be the minimum benefit for the particular product and the sponsor's proposed benefit will be the maximum benefit for the particular product. The difference between the minimum benefit and the maximum benefit will be the gap which may be payable by the patient.

34. During the negotiation process the PDNG will offer a proposed benefit amount and a recommended minimum benefit amount (the minimum benefit for the group/sub-group in which the sponsor's product is located). The proposed benefit amount represents the PDNG offer for the product to be listed as a no gap product. If the proposed benefit amount is not accepted and there is a potential for the product to be listed as a gap permitted product then the PDNG recommended minimum benefit will be put forward to the PDC. The potential gap would be the difference between the recommended minimum benefit and the sponsor's proposed benefit. It is expected that in many instances the PDNG proposed benefit and the PDNG recommended minimum benefit will be the same.

35. The PDNG and sponsor need to confirm in writing the benefit proposal going forward to the PDC. A proposal may include a maximum benefit as well as a minimum benefit. A response from the sponsor is required within 3 working days. This period may be shortened with the agreement of the sponsor.

36. For CAG products, the PDNG report to the PDC will be provided to the relevant

CAG for comment. The PDC is then able to consider the PDNG recommendations and clinical comments especially on those products where there is a potential gap and where the sponsor has provided additional clinical material. ***Is enough time being allowed for the CAG to comment and the PDC to review?***

37. For non-CAG products, the PDNG report is referred directly to the PDC for consideration. The PDC Secretariat will collate the recommendations of the PDNG and, where there are clinical issues, forward these to the relevant clinicians for consideration and advice to the PDC. ***It is important that the PoCE clinicians are practicing current experts in their field – our experience has shown this is not always the case.***

38. In providing recommendations to the PDC, the PDNG will also provide device utilisation data for currently listed comparator items in the report. ***AHIA utilisation data given to the PDNG is not always accurate. Furthermore, a particular item may differ clinically from the comparator, so why is the comparator utilisation data being used in negotiation?***

39. It should be noted that the PDNG is not able to make decisions on benefit amounts. It makes recommendations to the PDC and the recommended benefit amounts can be changed (up or down) by the PDC after considering other advice. ***"other advice" – Is this referring to the CAG's advice? Transparency of all advice is required by sponsor.***

40. The PDC may ask the benefit negotiators to reconsider some products where, for example, the CAG has advised that after reconsidering the available data, a particular product has a significant clinical use over the alternatives and needs to be available on the 'no-gap' list. ***Sponsor should be provided with meeting minutes and any advice given by the CAG to the PDNG.***

41. Sponsors will be advised in writing of the final PDC decision to recommend a gap or where the PDC's recommended minimum benefit differs from that signed off by the sponsor and the PDNG, before consideration by the Minister's Delegate, and be given five working days to consider reducing or eliminating any gaps.

42. The PDC will make recommendations to the Minister on devices to be listed with 'no-gap' and devices to be listed with gaps. Its recommendations will be based on the advice from the sponsors, the PDNG and the CAGs. ***Sponsor should have transparency of the advice being provided by the PDNG and CAG, and should be given a copy of all meeting minutes and recommendations.***

43. It should be noted that different no-gap benefit amounts can apply to products within the one group. This could be due to a number of reasons including a lower benefit proposed by a sponsor, a clinical difference recognised by the clinicians, or some difference in the product or the service associated with the product. In some cases the difference may be recognised through the use of a suffix. ***Specific reasons used by the PDNG to negotiate benefit amounts need to be transparent, and disclosed to the Sponsor early in the negotiation. This includes clinical advice provided by the CAG, utilisation figures and comparators.***

44. The suffix and annotations, where used by any of the CAGs, needs to be noted and taken into account where appropriate. Where suffixes and other relevant factors are taken into account, they should be specified in the PDNG report to the PDC including where there is a case for a 'no-gap' benefit differentiation on the

basis of these factors. ***Sponsor should be provided with a copy of the PDNG report to the PDC.***

45. Relevant information that could be taken into account by benefit negotiators includes:

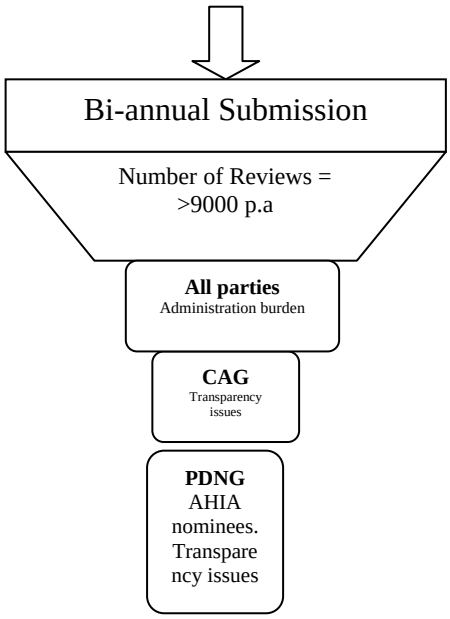
- technical aspects of the product, including:
  - the availability of technical support for it;
  - the ability of the product or instruments used to implant it to be linked to computer-assisted surgery;
  - the revision capability of a system; and
  - sterilization where this is included as part of the product;
- the sponsor's:
  - local research and development investment;
  - local training and education investment;
  - provision of patient education programs;
  - insurance; and
  - provision of clinical nurses;
- product packaging, including the number:
  - of units per pack;
  - sizes in the product range (indication of the patient populations in which the product can be used);
  - options within the range (indication of the number of clinical needs met by the product);
  - the product's terms of supply, including its supply as consignment stock; and
  - any applicable warranty.

Agreed by PDC – 26 June 2007

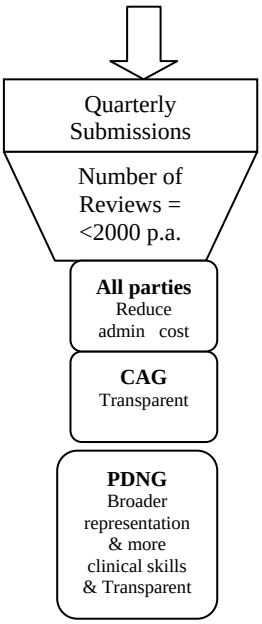
Appendix 3: An Optimal Model:

An improved model can be constructed from the existing arrangements. The essential reforms involve identifying the work that needs to be done then applying the available resources to that work. An improved model would also provide for increased transparency.

Current Model



Improved Model



Results:

Previous listed items - Industry
* Minimum benefit did not change 7749 (87%) products
* Minimum benefit rose for 511 (6%) products
* Minimum benefit fell for 617 (7%) products

Previous listed items - Medtronic
* Minimum benefit did not change 485 (90.6%) products
* Minimum benefit rose for 25 (4.7%) products
* Minimum benefit fell for 25 (4.7%) products

Expected Results:

* No. of reviews reduced to 2000 p a.
725 new items, 1275 previously listed.
* Eliminate bulk of no change reviews 7749.
* Allow CAG & PDNG time required to ensure required transparency.
* Reduce administrative burden for all.
* Independence of Negotiators.
* Greater adherence to time & process.
* Eliminate CAG & TGA duplication.