Johnson & Johnson
Family of Companies in Australia

Submission to the

Productivity Commission
Annual Review of Regulatory Burdens on Business – *Manufacturing and Distributive Trades*

31 July 2008

Our Credo

We believe our first responsibility is to the doctors, nurses and patients,
to mothers and fathers and all others who use our products and services.
In meeting their needs everything we do must be of high quality.
We must constantly strive to reduce our costs
in order to maintain reasonable prices.
Customers' orders must be serviced promptly and accurately.
Our suppliers and distributors must have an opportunity
to make a fair profit.

We are responsible to our employees,
the men and women who work with us throughout the world.
Everyone must be considered as an individual.
We must respect their dignity and recognize their merit.
They must have a sense of security in their jobs.
Compensation must be fair and adequate,
and working conditions clean, orderly and safe.
We must be mindful of ways to help our employees fulfill
their family responsibilities.
Employees must feel free to make suggestions and complaints.
There must be equal opportunity for employment, development
and advancement for those qualified.
We must provide competent management,
and their actions must be just and ethical.

We are responsible to the communities in which we live and work
and to the world community as well.
We must be good citizens – support good works and charities
and bear our fair share of taxes.
We must encourage civic improvements and better health and education.
We must maintain in good order
the property we are privileged to use,
protecting the environment and natural resources.

Our final responsibility is to our stockholders.
Business must make a sound profit.
We must experiment with new ideas.
Research must be carried on, innovative programs developed
and mistakes paid for.
New equipment must be purchased, new facilities provided
and new products launched.
Reserves must be created to provide for adverse times.
When we operate according to these principles,
the stockholders should realize a fair return.

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1. Submission Information

Organisation: The Johnson & Johnson Family of Companies in Australia

Type of Organisation: Group of Proprietary Limited Companies

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Declaration of Interest:

Companies in the Johnson & Johnson Family of Companies are engaged in business affected by a vast array of regulation and associated programs in manufacturing, wholesale trade, and retail trade of medicines, medical devices and diagnostics, and consumer healthcare products.

Note:

Each product referred to in this submission is the Registered Trademark of Johnson & Johnson.

2. The Johnson & Johnson Family of Companies

Worldwide

Caring for the world one person at a time inspires and unites the people of Johnson & Johnson.

We embrace research and science - bringing innovative ideas, products and services to advance the health and well-being of people.

Employees of the Johnson & Johnson Family of Companies work with partners in health care to touch the lives of over a billion people every day, throughout the world.

Our Family of Companies comprises:

- The world's premier consumer health company
- The world's largest and most diverse medical devices and diagnostics company
- The world's third-largest biologics company
- And the world's sixth-largest pharmaceuticals company.

We have more than 250 operating companies in 57 countries employing 119,200 people.

In 2007 we invested US$7.68 billion in research.

Our worldwide headquarters is in New Brunswick, New Jersey, USA.

In Australia

Johnson & Johnson Pty Ltd became an Australian corporate entity in 1931.

Today there are more than 1500 J&J employees in Australia and New Zealand and annual turnover of more than AUD$1.1 billion.

There are six health and medical care focused operating companies in Australia: Johnson & Johnson Medical; Janssen-Cilag; Johnson & Johnson Pacific; Johnson & Johnson Research; Tasmanian Alkaloids; and Ortho-Clinical Diagnostics.

In 2005, Access Economics reported that during 2004, Johnson & Johnson in Australia accounted directly for gross value added of $327 million, GDP of $366 million and the employment of 1,313 full-time equivalents (FTE).

In addition, the flow on from inputs of domestically produced goods and services into Johnson & Johnson activities indirectly contributed additional gross value added of $253 million, GDP of $259 million and the employment of 2,772 FTE.

Combining the direct and indirect contributions, in 2004 Johnson & Johnson contributed gross value added of $580 million, GDP of $624 million and employment of 4,085 FTE to Australia.

We now outline the lines of business and companies within the Johnson & Johnson Family of Companies in Australia.

Pharmaceuticals

Janssen-Cilag Australia

Janssen-Cilag Pty Ltd (JCA) is a research-based company that markets pharmaceuticals for a range of conditions in mental health, neurology, haematology, gastroenterology, virology, and pain management. One of its key focus areas is biotechnology, which represents the promise of entirely new and highly targeted therapies for a range of diseases. At the same time, innovative genomics tools are already beginning to revolutionise and advance the discovery of pharmaceutical medicines.

Johnson & Johnson Research

Johnson & Johnson Research Pty Ltd (JJR) was incorporated in 1987 to identify new medical discoveries in Australia and facilitate their commercial development into new products for J&J. The role of the company was expanded in 1992 with the establishment of the JJR laboratories with a focus on genetic approaches to diagnosis and treatment. JJR has purpose-built research facilities at the Australian Technology Park in Sydney and a workforce of 75, most of whom have tertiary credentials in science or medicine.

The discovery and early development projects in JJR arise from the company's unique capabilities in utilising DNA and RNA to regulate and measure gene function and expression.

As an R&D hub for J&J in the Asia Pacific with unique scientific expertise and a strong track-record in innovation, JJR contributes substantial strategic value to J&J and performs a central role in the region by sourcing high value new business opportunities for global operating companies. These include contract research and outsourcing, licensing of new molecular entities, and discovery & development of research collaborations.

Tasmanian Alkaloids

Tasmanian Alkaloids Pty Ltd is an advanced agricultural production and research & development company. It extracts alkaloids (morphine and thebaine extract) from poppies. Some of this product is converted to active pharmaceuticals (codeine phosphate and buphrenorphine) with around 99% of the product exported.

In 1995, Tasmanian Alkaloids and JJR initiated a project to develop a high-thebaine poppy. In sampling the alkaloid content of thousands of plants, one plant was found to have a high content of thebaine and no morphine, and the first commercial crop of these unique poppies was harvested in 1998. The new plant revolutionised thebaine production and today it has up to 80% of the worldwide market for Oxycodone raw materials.

Tasmanian Alkaloids is presently the largest manufacturer of active pharmaceutical ingredients in Australia and the largest exporter of codeine and thebaine in the world.

Medical Devices & Diagnostics

Johnson & Johnson Medical

Johnson & Johnson Medical Pty Ltd (JJM) is a major provider to the Australian health care system through both the provision of products and the development and implementation of support services for the medical community. Each year, JJM reinvests more than ten per cent of its sales in Australia to provide training and other assistance to local doctors. It is focused on a broad range of medical products and through a number of separate groups: Ethicon wound closure and wound management; Ethicon Endo-Surgery minimally invasive technology, laparoscopic instruments and mechanical staplers; Gynecare and Breastcare women's health products and antiseptic products; Cordis cardiology, endovascular, electrophysiology and neuro-radiology; and DePuy Australia, a leading developer of state-of-the-art technologies for joint reconstruction which markets a range of orthopaedic products.

JJM also supports clinical research programs in Australia across all business franchises. From involvement in global programs, first-in-human studies of new innovative technologies, to support original research ideas from Australian clinicians and specialists. JJM is particularly proud to have a long track-record of partnering with Australian surgeons to bring new and innovative devices to the global marketplace.

Ortho-Clinical Diagnostics

Ortho-Clinical Diagnostics (OCD) and Veridex LLC supply professional in vitro diagnostic instrumentation and related supplies to hospital laboratories, private pathology laboratories, and blood donor centres. Products include reagents used for determining patient blood groups and the compatibility of blood units prior to blood transfusions, screening of blood for infectious agents (eg. Hepatitis C), and reagents and instrumentation used for clinical chemistry, endocrinology, serology and oncology blood testing.

Consumer Healthcare

Johnson & Johnson Pacific

Johnson & Johnson Pacific Pty Ltd (JJP) is the largest over-the-counter supplier to retail pharmacy in Australia serving all community pharmacies and being in the top thirty suppliers for manufactured goods to grocery supermarkets. JJP is committed to providing the best service, programs and advice to consumers, customers and the community, and is dedicated to bringing to market innovative healthcare solutions.

Our broad product range spans across baby, beauty, oral care, smoking cessation, upper respiratory, gastro intestinal, eye care and general medicine categories. Among our most famous brands are the Johnson's Baby® range, Band-Aids®, Listerine® and Reach®.

3. Johnson & Johnson and Regulation

Strong and effective regulation has been a key concern for our company since its foundation in 1886.

We promote strong and effective regulatory bodies and appropriate regulation that supports efforts to enhance access to health care.

We therefore welcome the focus of this Review on enhancing productivity and decreasing regulatory burdens in manufacturing, retail trade and wholesale trade.

We commend the Australian Government and the Productivity Commission for conducting this important and timely review.

In this submission we raise ideas and recommendations for improving productivity and reducing regulatory burdens in Australia.

We have not raised every productivity related issue that concerns us. It is not feasible to do so and other submissions will address further issues.

We have noted and broadly support the submissions made by the following related industry bodies:

- Medicines Australia (MA); and
- Medical Technology Association of Australia (MTAA)

Further, two recent submissions made by the Johnson & Johnson Family of Companies contain many recommendations that pertain to regulatory improvements (among other issues):

1. *Submission to The Review of the National Innovation System*

   (http://www.innovation.gov.au/innovationreview/Documents/524-Johnson_and_Johnson.pdf)

2. *Submission to The National Health & Hospitals Reform Commission*

   (yet to be made available online by the NHHRC – a copy can be supplied upon request)

We encourage the Commission to have regard to these two submissions.

4. Therapeutic Goods Regulation - Medicines

4.1 Introduction

Johnson & Johnson is pleased to note the many issues considered by the Commission in its draft report.

We address these issues and add to certain issues, where relevant, and do so under the same headings appearing in the Commission's Draft Report.

4.2 Timeliness and cost of manufacturing audits/GMP assessments

Janssen-Cilag believes it is of utmost importance for the TGA to provide an efficient and effective GMP Clearance system with a transparent risk assessment process to ensure continuity of supply of therapeutic goods that are vital for Australian patients.

Johnson & Johnson shares the concerns expressed by industry to the Commission relating to the: uncertainty around expiry dates for GMP Clearances; the TGA no longer respecting the acceptability ratings assigned by the US FDA; problems in obtaining Establishment Inspection Reports (EIRs); contracting manufacturers not being able to control quality of some GMP documentation; and unnecessary TGA audits having to be arranged.

We agree that "*there would be significant cost savings for many pharmaceutical companies if the TGA were to more widely recognise prior certification processes conducted overseas by bodies assessed as suitably competent.*" However, the application of the "risk matrix" (and we note the basis of this construct is not transparent to companies) to decide the expiry of GMP Clearances means that in most instances, the renewal dates of GMP Clearances are no longer aligned with the re-inspection schedules of overseas inspecting health authorities.

We also agree that the TGA needs to commit to specific desktop audit GMP Clearance timeframes. Such targets are important for measuring performance of the service provided by the TGA.

With regards to the example given of "*Old or dated evidence……*", in most cases, sponsor companies do not intentionally submit outdated documents but are usually put in a situation where there is no other choice as the documents submitted are the only ones available and the fact that overseas regulatory inspectors work according to their own priorities and not those requested by companies operating in Australia. We would therefore disagree that such a practice, which is an indirect result of the existing GMP clearance regime, creates a "very uneven regulatory playing field for Australian medicine manufacturers." In our opinion, it creates an uneven regulatory playing field for Australian sponsors who wish to register overseas manufacturing sites that do not have their health authority inspection schedules aligned with the expiries of GMP Clearances assigned by the TGA, via the application of the "risk matrix".

We support the stance of the Commission that "*greater consideration also needs to be given to the requirements Australia is placing on overseas plants relative to requirements imposed by other developed countries seeking to maintain similarly high standards of safety for medicines supplied to their domestic market, for example the US and EC countries.*" We concur with the suggestion that Australian sponsors have a harder time registering overseas plants than pharmaceutical manufacturers anywhere else in the world.

The application of the risk-based criteria creates a lot of uncertainty relating to expiry dates for GMP Clearances. In addition, compounded by current delays in the processing of desktop audits, it has become a big challenge for Johnson & Johnson to plan our Clearance renewal activities accordingly.

In addition, we raise these concerns:

Inconsistencies in the risk minimisation approach adopted by the Office of Manufacturing Quality (OMQ)

On the one hand, desktop audits and TGA inspections are being made compulsory for manufacturers as described in the 16th edition of the Guidance on the GMP Clearance of Overseas Medicine Manufacturers. However, due to the TGA's inability to efficiently process large volumes of desktop audits applications, they have been granting, on a case-by-case basis, extensions of expired Clearances. Similarly, due to the shortage of auditors available to perform overseas manufacturer inspections, the TGA have been issuing GMP Pre-Clearances without prior inspection. Such practices, are inconsistent with the risk minimisation approach that the TGA is striving to adopt. Additionally, we feel that the TGA should not be implementing requirements that they do not have the adequate resources to cope with.

Short response timeframes when random TGA inspections are announced

According to the 16th edition of the Guidance on the GMP Clearance of Overseas Medicine Manufacturers, "*The TGA reserves the right to conduct an audit (inspection) of any overseas manufacturer, irrespective of the documentary GMP evidence submitted to the TGA, even if there is a current GMP Clearance*". In our experience, when Janssen-Cilag was informed of a random inspection initiated by the TGA, we were given a very short timeframe (5 working days) in which to respond. This is of concern given that the typical cost of audits may range in the tens of thousands of dollars and sometimes into the hundreds of thousands, depending on the duration of the inspection as well as the number of TGA representatives performing the inspection. Decisions involving such large sums cannot easily be made, particularly in the case of multinational companies where input may be required from Head Office.

Frequent changes/ updates to the Guidance on the GMP Clearance of Overseas Medicine Manufacturers without sufficient consultation with industry

This document has been updated 4 times in the last 2 years and only with the latest edition, i.e. the 16th edition, was industry given a small window of opportunity to comment. We believe that the TGA needs to take a true consultative approach in adopting new/revised Guidelines by giving companies the opportunity and sufficient time to comment on changes and new requirements. In addition, the TGA should allow for a transition period for new requirements to be operational. This would provide multinational pharmaceutical companies with sufficient time to familiarise their Head Office functions with the new requirements and to allow generation of new information to meet these additional requirements.

The Commission's draft responses in this area are largely positive and broadly supportable.

We suggest the third point of draft response 4.1 be amended to "*wider recognition of international processes and acceptance of GMP certificates or inspections where conducted by bodies assessed as suitably competent, for example those acceptable to the US Food and Drug Administration.*" This change reflects the fact that the US FDA no longer issues GMP Certificates.

Recommendation 1:

A true and timely consultative approach is taken by the TGA when revising the Guidance document on the GMP Clearance of Overseas Medicine Manufacturers and before adopting new guidelines.

4.3 Concerns about PBS listing and pricing processes

In relation to Weighted Average Monthly Treatment Cost (WAMTC) measures, Johnson & Johnson notes positively the Commission's focus on taxpayer's getting the best value for PBS listed medicines.

This same focus is central to the reforms to the PBS implemented since last year and which continue in implementation for the next few years. Under the reformed arrangements, and in respect of the F2 formulary of medicines, price cuts, price disclosure, and the application of a weighted average price will be applied. These measures, taken together, will meet this focus and render WAMTC measures unnecessary.

For this reason, and having regard to the administrative burden of WAMTC compliance (as noted by the Commission), we believe that there is little justification for WAMTC to be maintained.

Recommendation 2:

In light of the PBS reforms and having regard to regulatory burden, the WAMTC methodology should be removed from the system.

4.4 Delays in achieving PBS listing due to overlapping procedures

There is scope to improve and better integrate the two key processes through which innovative medicines become available to Australians. The TGA's product registration process and PBAC product reimbursement process could each be more efficient and internationally competitive. Further, as two inter-related systems, they can be more streamlined and complementary.

Presently, the TGA process time frame for completion is 255 days and the PBAC process takes 17 weeks (pre-PBAC meeting). It is envisaged that through better system design, integration and execution the total time period to facilitate access to innovative medicines could be reduced by about 6 months.

As the Commission has noted, we await the output of the work of the Access to Medicines Working Group on this issue. This is an important opportunity to improve two key regulatory systems in Australia.

We believe the Commission's draft response 4.3 should be strengthened to reflect the notion that such a streamlined system be the norm, not the exception (or merely on request). This would help to ensure that in terms of delivering timely access to medicines, Australia's regulatory system would be among world's best practice.

We also consider that the suggested risk of such an approach would be substantially outweighed by the benefits to patients of earlier access to essential medicines. Further, the Commission's suggestion that industry should pay on a case by case basis for such regulatory streamlining and coordination of systems would not be a positive addition to the regulatory environment, indeed it would be an additional cost of doing business. This stands against the intentions of the Commission's Review as we understand it.

We note the Commission's reference to the cost recovery for PBAC services announced in the May 2008 Budget. Johnson & Johnson strongly supports the recent submission of Medicines Australia (to the Senate Community Affairs Committee) opposing the introduction of such arrangements.

Recommendation 3:

A system whereby TGA and PBAC processes are streamlined and coordinated be the norm (rather than the exception).

4.5 Concerns about marketing and advertising rules

Johnson & Johnson welcomes the Commission's statements concerning the imposition of the least compliance burden in meeting Medicines Australia Code requirements (and particularly those concerning the ACCC requirements).

In addition we wish to raise an issue of concern having regard to market rules.

Codes of conduct have an important role to play in raising levels of confidence in the healthcare system. We adhere to industry codes including the MA and MTAA codes. We note however that some market participants are not presently required to meet all such code requirements. This is an area of concern that warrants reform. Sound regulation should be applied consistently and fully across all the market.

In our recent submission to the National Health & Hospitals Reform Commission, we asserted that, in the interests of ethics and respect, the healthcare system should only deal with those companies that have committed to compliance with relevant and appropriate codes of conduct.

Recommendation 4:

All market participants should be required to comply in full with relevant and appropriate codes of conduct.

5. Therapeutic Goods Regulation – Medical Devices

5.1 Introduction

Medical device regulation in Australia is harmonised with the European Community (EC) Medical Device Directive (MDD). The MDD is for the most part consistent with the international model developed by the Global Harmonization Task Force (GHTF) however there remain some fundamental differences between the MDD and GHTF models such as the classification system and definition of the central circulatory system.

In a market where over 90% of medical devices are imported and Australia represents less than 2% of the global medical device market it would be most effective for the TGA to focus on working with reputable overseas regulatory authorities and Notified Bodies to develop a common understanding of, and confidence in each other's processes and decision making. This would maximise opportunities for mutual recognition agreements to be put in place where acceptance of each other's product evaluations and audits would be mutually beneficial in increasing efficiency and efficacy, managing resources, containing fees and charges and making new medical technologies available to Australian patients as quickly as possible.

5.2 Class III Devices

Level 2 Application Audits are mandatory for Class III devices that do not contain a medicine or material of animal, human, microbial or recombinant origin.

As stated in Australian Medical Device Guidelines *Guidance Document 2 Application Audits,* the intent of this process is to "confirm that the manufacturer of a medical device has carried out the conformity assessment procedures appropriate to the class of the medical device" and goes on to qualify this statement by stating that "during an application audit the TGA will not undertake any assessment or activity that would normally be performed by the manufacturer or the TGA as part of a conformity assessment procedure".

In most cases, overseas manufacturers undertake the appropriate conformity assessment procedures for Class III devices by having Quality Management System certification issued by a Notified Body (NB) together with the preparation of a Design Dossier comprising technical product specific documentation for evaluation by the NB. This evaluation results in the NB issuing a Design Examination Certificate and a Summary Technical Report specifically required for inclusion in the Level 2 Application audit documents required by TGA. The costs and turnaround times associated with the Notified Body process are as follows:

Standard Notified Body review: US$15,000 (estimate based on US$2820 per day)
Turnaround Target: 70 – 90 days

Fast Track Review: US$30,000 (estimate based on US$7050 per day)
Turnaround Target: 45 days

Standard Summary Technical Report: US$2300 (70 – 90 day turnaround)
Fast Track Summary Technical Report: US$4725 (25 day turnaround)

Once CE Marking via this process is achieved, the Class III device application can be lodged electronically via the DEAL system. The TGA then issues a Section 41JA letter requesting the supporting documentation.

Rather than the audit process being a check that the appropriate conformity assessment process has been applied, the Level 2 Application Audit process is a duplicative evaluation process where much of the same documentation that was assessed by the NB in the Design Dossier review is re-evaluated by the TGA.

The overall cycle time for TGA approval for new products (not re-registrations) at present is approximately 6 months.

Since the TGA evaluation can only commence once the Design Dossier review has been completed and the Design Examination Certificate issued, the sequential nature of these two processes means that products are launched in Australia 6 – 9 months later than they are available in Europe. With the average lifecycle of a medical device being 18 months, the duplicated process conducted in Australia means that, not only are new technologies not available to Australian patients until much later than European patients but one third of the investment recovery period is lost.

It should also be noted that a submission and single evaluation fee to a NB would typically cover a 'family' of like products. Due to the restrictions posed by the use of variants in Australia, one Design Examination Certificate frequently requires the lodgement of multiple applications with the associated multiple application and evaluation fees.

On the basis that the Australian medical device market represents less than 2% of the global market, all opportunities to leverage acceptable international processes should be maximised. On this basis, an approval time of 3 months would be achievable and acceptable.

Recommendation 5:

Streamline medical device approvals in Australia by wider recognition and acceptance of international processes, audits and certification of medical devices by reputable overseas regulators.

Recommendation 6:

Accepting the Notified Body's Quality Management System certification together with the Design Examination Certificate as sufficient evidence that a Class III device has been through an appropriate conformity assessment procedure and limit the Level 2 Application Audit to be a checking process rather than an evaluation.

5.3 Notified Body Quality Audit Reports for Overseas Manufacturers

Until recently TGA has accepted Quality Management System certification and surveillance audit reports from highly regarded NB's together with the company's corrective action plan and NB close-out. Recently however, Johnson & Johnson has been notified of TGA's intention to conduct overseas audits of three Johnson & Johnson manufacturers located in Puerto Rico, Brazil and the USA at a cost of approximately $20,000 per audit. The Australian sponsor is responsible for funding the travel, accommodation and allowance of the auditor/s, assessor preparation at $310 per hour plus an audit fee of $6,480.

These audits are all in relation to the full conformity assessment by TGA of medical devices containing a medicine or material of animal, human, microbial or recombinant origin. However, all facilities are regularly audited by a reputable NB with their audit reports and recommendations available for review by TGA so we question what is achieved by the duplication of this expensive process.

Recommendation 7:

That TGA work with overseas Notified Bodies and authorities to develop harmonised procedures for manufacturer audits to eliminate the need for costly duplication.

Recommendation 8:

That TGA firstly review audit reports, corrective action plans and close-out reports from overseas authorities and provide justification to the sponsor for why those reports are not considered satisfactory before determining that a TGA audit of an overseas manufacturer is required.

5.4 Mutual Recognition Agreement

The Australia-EU Mutual Recognition Agreement provides a rapid path to TGA approval for Class III devices where the legal manufacturer is located in the EU and the device is substantially manufactured within the EU. Class III devices that have been reviewed and CE marked by a Notified Body can have a Mutual Recognition Agreement (MRA) Certificate issued which is lodged with TGA and the product approved without any additional evaluation within 2 weeks. Johnson & Johnson uses this abbreviated process wherever possible.

This arrangement based on a Trade Agreement between Australia and the EU has resulted in a trusting mutual understanding between the TGA and NB's that devices have been through a conformity assessment that meets the TGA's requirements without further evaluation.

Class III devices from US manufacturers go through the identical process of Design Dossier review by a NB however are then required to go through an additional costly 6 months review process by TGA in order to be included in the Australian Register of Therapeutic Goods (ARTG).

Recommendation 9:

That TGA compare post market safety and performance data to determine whether the requirement for US manufactured Class III devices to go through an additional 6 month evaluation process, when the safety and performance of the device has already been established by a NB in exactly the same manner as products from the EU, is justified.

Recommendation 10:

That TGA investigates whether an equivalent MRA process can be established between Australia and the US in order to eliminate the need for a duplicative and costly process which delays the availability of new and innovative technologies for Australian patients.

5.5 Inconsistent Definition of the Central Circulatory System

The Australian definition of the Central Circulatory System includes the *ilica communis* or common iliac vessel whereas the MDD definition stops at the *abdominalis aorta* and does not include the common iliac. Therefore devices that are indicated for use in the common iliac such as peripheral vascular stents are Class III in Australia and Class IIb in Europe.

Within the framework of their certified Quality Management System, overseas manufacturers of Class IIb devices create and sign-off a Technical File in order to complete the appropriate conformity assessment procedure for supply in Europe.

In order to complete the appropriate conformity assessment procedure as a Class III device specifically for Australia, the manufacturer is required to undertake a great deal of additional work to prepare a Design Dossier for the product and submit it to the NB for evaluation in order to have a Design Examination Certificate and Summary Technical Report issued.

It is unrealistic to expect the source company to divert resources onto a lengthy and costly project specifically to support a very small segment of the global market (<2%) and to request that the project be given a high priority in order to reduce delays to the introduction of new peripheral vascular products in Australia.

The only alternative is to submit an application for a Full Conformity Assessment certificate from TGA, which would also involve the preparation of additional documentation by source company specifically for review in Australia.

In our experience such evaluations are taking at least 12 months to be completed and the most recent three applications have resulted in the TGA scheduling audits of the overseas manufacturer. The additional burden on the source company together with the unacceptably long TGA evaluation time and cost associated with full conformity assessment by TGA makes this option prohibitive.

Recommendation 11:

That TGA reconsider their definition of the Central Circulatory System by examining post market data related to devices used in the common iliac to determine if including such products as high risk Class III devices is in fact justified.

Recommendation 12:

Make the TGA definition of the Central Circulatory System consistent with the MDD definition to eliminate the need for additional regulatory burdens for overseas manufacturers to support a very small segment of the global market.

Recommendation 13:

That significantly abbreviated documentation requirements and full conformity assessment evaluation processes be developed by TGA to facilitate the rapid approval of products that are Class III in Australia but lower class in Europe.

5.6 General Issues Regarding Communication and Transparency

Poor communication with regulators

There have recently been a number of structural and personnel changes at the TGA and it is at times unclear whom the most appropriate person is to contact with an enquiry.

TGA personnel do not have a telephone voicemail system therefore it is impossible to leave a message directly with the person you are trying to contact.

We have received push back from TGA when requesting appointments to meet with TGA face-to-face. Meeting in person with TGA staffers enables a focussed and detailed discussion of an issue in order to establish a clear mutual understanding from both perspectives.

Inconsistent and untimely advice

When requesting advice on matters of policy or procedure, some TGA staff are reluctant to put that advice in writing and the company is left to make business decisions based on verbal advice. In general, we experience a very poor level of response to email requests for information or action.

We have had occasions where we have received written advice from TGA on matters of policy, only to find out later that the advice is incorrect but we have not been advised of the error.

There is lack of transparency around policy decisions and recommendations that arise from the regular TGA Management Review meetings. It would be extremely useful if the decisions of this group could be disseminated to industry so that all companies have access to the same information.

Deployment of Essential Resources at TGA

Current structural and personnel changes at TGA aimed at clearing the backlog of applications submitted for re-registration prior to the October 4, 2007 deadline is having a negative impact on the evaluation times of new and innovative products.

The amendment to the Act allows for sponsors to continue supplying products beyond the October 4, 2007 deadline as long as an effective application was in place prior to the deadline. Therefore the delay in the evaluation and approval of these applications has no impact on the supply of these products.

However, inappropriate deployment of essential resources in the application coordination and device evaluation sections resulting in prioritisation of re-registration applications over new product evaluations is having a very real impact on the availability of new and innovative technologies for Australian patients.

Recommendation 14:

TGA publish on the website a current organisation chart together with a list of key personnel, their role, direct contact details and the specific areas for which they are responsible.

Recommendation 15:

That TGA implement a voice mail system for all employees to facilitate communication.

Recommendation 16:

That TGA implement a monitoring system to ensure that emails are responded to promptly.

Recommendation 17:

That policy decisions and advice are supplied to the requestor in writing.

Recommendation 18:

That policy decisions resulting from TGA Management Review meetings are promptly published on the TGA website.

Recommendation 19:

That a workflow system for application tracking be implemented in order to provide transparency for sponsors and priority for new product applications ahead of re-registration evaluations.

5.7 Health Outcomes

Figure 4.3 of the draft Productivity Commission report does not accurately reflect the regulatory and reimbursement processes for medical technologies.

Page 28 of the Report of the Medical Devices Industry Action Agenda (2006) shows the current TGA, MSAC and PDC timeframes for the assessment of new medical procedures and devices (**Attachment 1**).

Page 29 of the Report of the Medical Devices Industry Action Agenda (2006) shows the relationship between TGA, MSAC and PDC committees for medical procedures, devices and prostheses (**Attachment 2**).

5.8 Draft Response 4.7

Johnson & Johnson supports HTA processes that ensure Australians have timely, affordable and equitable access to safe and effective medical technologies. Whereas other countries with larger healthcare sectors have only one HTA body, Australia has four (five, if the Pharmaceutical Benefits Advisory Committee is included) government funded HTA groups. With the overlapping objectives of the TGA, MSAC, PDC and ASERNIP-S, and their responsibilities unclear, it is essential that regulations relating to funding and reimbursement decisions are streamlined to reduce inefficiencies and excessive delays in access to new technology avoided due to duplicated assessment processes.

We acknowledge the role of evidence-based medicine (EBM) to facilitate informed decision making in the complex area of healthcare delivery and outcomes. However, in the absence of high quality evidence for the majority of medical devices, existing HTA processes are proving to be an effective block to the introduction of new technologies in Australia. Unlike medicines, randomised controlled trials (RCTs) or gold standard clinical evidence is often not available for medical devices, particularly for new products. Alternative sources of data to demonstrate clinical efficacy/ effectiveness of a medical technology should be considered.

One possible solution may be the granting of provisional listing for new procedures and technologies, which is conditional upon collection of data to support continued reimbursement. Resolving the issue of clinical evidence requirements requires the full involvement from all the stakeholders including medical device suppliers, to ensure faster patient access to new and innovative medical technologies.

The majority of reimbursement submissions to the Medical Services Advisory Committee (MSAC) and the Prostheses & Devices Committee (PDC) come from industry. We suggest that as part of the HTA review processes, a Working Party with representation from industry and government, be established to consider and implement recommendations following their reviews, and to explore alternative methods and processes of fast-tracking market access of innovative medical technologies.

Recommendation 20:

New procedures and technologies are granted provisional listing, which is conditional upon collection of data to support continued reimbursement.

Recommendation 21:

A Working Party with representation from industry and government, be established to consider and implement recommendations following their reviews, and to explore alternative methods and processes of fast-tracking market access of innovative medical technologies.

5.9 Assessment for funding/reimbursement of non-prostheses

There is currently no reimbursement mechanism that permits high cost, single use devices to be covered by health funds. In the absence of an alternative reimbursement pathway, we believe the most appropriate solution is to accommodate these items on an 'essential care list'. This would allow for consistency in a reimbursement process that is defined by a set of criteria based of improved health outcomes, and not by whether a device is a 'prosthesis', which is the main factor that determines eligibility for listing on the Prostheses List.

An example of an important technology that does not receive reimbursement in the private sector is electrophysiology ablation catheters for treatment of atrial fibrillation. These devices are used in procedures that demonstrate improved health outcomes, but are not covered in contractual arrangements between private hospitals and health funds. In contrast, electrophysiology procedures are performed in the public sector, however treatment of patients suffering from atrial fibrillation is limited by budgetary constraints.

Recommendation 22:

In the absence of an alternative reimbursement pathway, that an 'essential care list' be established to provide funding for high cost single use devices.

5.10 Case Study: Private Reimbursement for Electrophysiology Cases

Background

In recent years, electrophysiology catheter ablation procedures (as opposed to procedures involving cardiac rhythm management devices) have caused issues for private hospitals due to a lack of consistent reimbursement for the catheters involved by health funds. This is largely unique to private hospitals, as public hospitals do not have the same funding arrangements.

EP Procedures

Until the late 1990s, EP procedures were relatively simple, involving only 3-4 low cost catheters. It has been on this low-cost basis that health funds have traditionally reimbursed EP procedures, largely through a case payment basis. This technology facilitated the treatment of simple tachycardias such as SVTs and atrial flutters.

In the last decade though, technology has advanced to treat far more complex arrhythmias, including atrial fibrillation and ventricular tachycardias. Foremost among these advances have been catheters such as LASSO® circular mapping catheters (for the diagnosis of atrial fibrillation) and THERMO-COOL® ablation catheters (for safer and more effective ablation). However, by far the most revolutionary advance in the treatment of arrythmias has been the advent of 3D Mapping Systems, such as the CARTO® XP System, and the 3D catheters (NAVI-STAR® catheters) that are used with them. This advanced technology has increased treatment success rates and indeed facilitated the treatment of these arrythmias. Not surprisingly, this enabling technology has also increased the cost of procedures.

Given the prevalence of these advanced cases, this will be an ongoing issue for private health care. By way of example, for the purpose of this paper, we examine here the most prevalent advanced EP disease treatment, for the arrythmia known as atrial fibrillation.

Atrial Fibrillation

- Atrial Fibrillation (AF) is the most common of all heart rhythm disturbances or ‘heart arrhythmias’, affecting 2% of the Australian population. The prevalence of the disorder increases with age, and it is particularly common in older people, affecting 10% in people aged over 75 years. It is estimated that 165,000 Australians currently suffer from AF.

- In Australia, AF is a major health problem, and is a contributing cause of 6,000 strokes a year – the risk of stroke for people with AF is 5 to 6 times higher than for the general population. In addition to a high risk of stroke, AF is also associated with frequent hospitalisation and reduced quality of life due to heart failure (eg. fatigue, malaise, shortness of breath, dizziness), or palpitations.

- Until recently, the only option for treatment was to control the symptoms through drug therapy. These drug therapies for AF were limited to suppression of the symptoms and were not curative, and AF tended to recur within one to two years in at least 50% of patients. If effective, antiarrhythmic drug therapy is a life-long requirement and has significant healthcare cost implications, estimated to be $1,500 per patient per annum.
- Recent advances have meant that the optimal treatment for AF is now a curative treatment through a catheter ablation procedure, which has now been established to be superior in terms of mortality, morbidity, recurrent AF and quality of life compared to antiarrhythmic therapy.
- In progressing from controlling the symptoms of AF to curative treatment, we estimate that the healthcare system will achieve a cost saving of approximately $22,400 over the lifetime of each patient. Given the current incidence, this could represent savings to the healthcare system of up to $3.7 billion. This represents only direct costs, and not indirect costs of curing AF such as return to work.
- From MBS data, it is estimated that approximately 670 RFA cases were performed on private patients with AF treated in 2005/6. The number of public cases treated in public hospitals is estimated to be about the same. The number of cases is expected to grow at between 10% and 20% per year.

In summary, AF imposes a significant and increasing economic burden on Australia's healthcare system due to a rapidly ageing population, the associated increase in prevalence of AF and other underlying conditions including stroke, hypertension, heart disease and heart failure.

Insufficient healthcare support for private EP procedures

The increasing burden of AF is placing pressure on the healthcare system. However, as identified above, the most pressure is being placed on privately insured patients, who are frequently unable to receive the treatment that is now standard and is provided at public hospitals due to a lack of private healthcare support.

Part of the reason for the insufficient level of private healthcare support is that previous years' case cost comparators are inappropriate – it is comparing lower-technology cases with the higher-technology cases that are now being performed. Subsequently, health-funding arrangements are frequently based on outmoded approaches to treatment.

However, far more significantly, because the catheters used in the treatment of these advanced EP cases are not permanently implanted, they do not meet the listing criteria for the Prostheses List, and are therefore not automatically funded by health funds. This is despite the fact that these catheters are absolutely essential for the successful treatment of AF and other advanced arrhythmias.

For this reason, case payments for EP procedures have frequently been inadequate. Some health funds and hospitals have negotiated arrangements whereby catheter costs are covered by ex-gratia payments. However these arrangements vary greatly between hospitals and health funds, and range from no reimbursement at all, to partial reimbursement to total coverage for these catheters and technologies. In our experience, this coverage is becoming increasingly difficult as demand for treatments increase.

6. Conclusion

The Johnson & Johnson Family of Companies in Australia supports strong and effective regulation.

We are deeply committed to working with governments and other stakeholders towards enhanced productivity and reduced regulatory burdens.

In this spirit, we thank the Commission for the opportunity to submit and we are pleased to commend these ideas and recommendations to the Commission for consideration.

The Johnson & Johnson Family of Companies in Australia would be pleased to assist and work with the Commission and the Government to:

1. amplify and/or clarify these submissions;
2. attend hearings to speak to these submissions;
3. provide expert advice in relation to these submissions or matters of therapeutic goods regulation more generally; and
4. otherwise contribute to the development and implementation of stronger and more effective regulatory systems in Australia.

Johnson & Johnson
Family of Companies

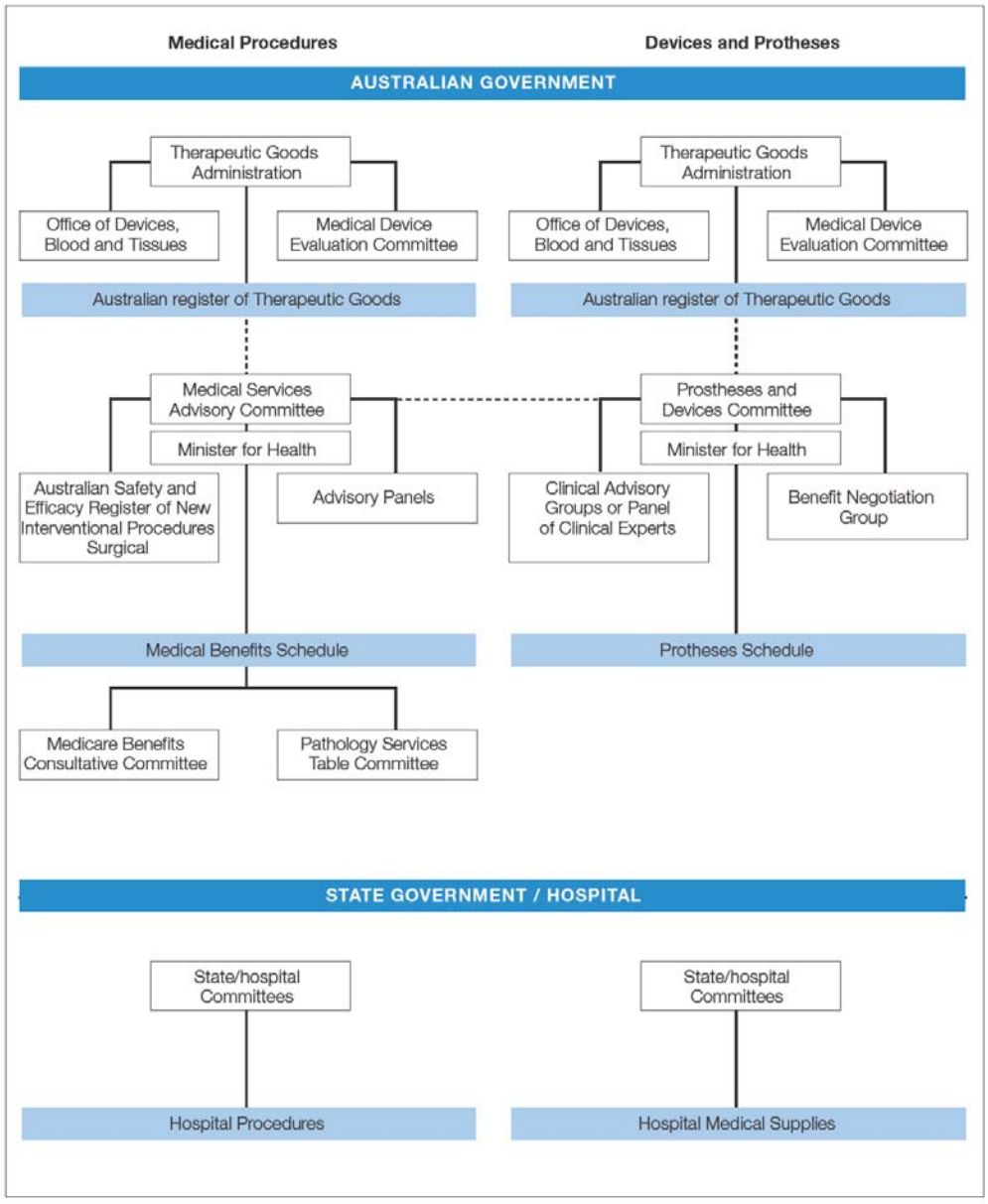
Attachment 1

CURRENT TIMEFRAMES FOR THE THERAPEUTIC GOODS ADMINISTRATION, MEDICAL SERVICES ADVISORY COMMITTEE, AND PROSTHESES AND DEVICES COMMITTEE.

DATE	THERAPEUTIC GOODS ADMINISTRATION (TGA)	MEDICAL SERVICES ADVISORY COMMITTEE (MSAC)	PROSTHESES AND DEVICES COMMITTEE (PDC)
Month 0	Class 3 devices: Receipt and accept, assess and finalise applications requiring Level 2 application audit.		
Months 3 to 6	Submissions finalised within 60 days of receipt.		
Month 4		Application to the MSAC received by Medicare Benefits Branch, Department of Health and Ageing.	
Month 4		Written acknowledgment of application and number allocated to application.	
Month 4		Written information of completion of Stage One—application has been accepted as being suitable.	
Month 4		Medicare Benefits Branch Project Officer allocated.	
Month 4		Letters sent out to relevant organisations and associations for nominations for the Advisory Panel.	
Month 4		Evaluators appointed and asked to draft a protocol.	
Months 6–9		First meeting of the Advisory Panel and evaluators—refinement of draft protocol.	
Months 7–10		Draft protocol sent out to application sponsor with two-week deadline.	
Months 7–10		Comments on draft protocol reviewed by chairperson of the Advisory Panel and other members of panel if necessary.	
		Evaluators' draft Assessment Report presented to the Advisory Panel.	
		Any reviews of draft Assessment Report carried out by the evaluators.	
		Reviewed draft Assessment Report sent out to application sponsor with four-week deadline.	
		Comments from application sponsor responded to by evaluators.	
Meeting every 3 months		Assessment Report (complete with conclusions by the Advisory Panel) and sponsor's comments presented to MSAC meeting.	
		Recommendation of MSAC meeting sent to the minister.	
		Minister's decision made known to sponsor.	
		Positive recommendations forwarded to the Medicare Benefits Consultative Committee for setting of fee and drafting of the wording for the Medical Benefits Schedule (MBS) item number.	
		Medicare Benefits Consultative Committee formed.	
Feb or August		MBS item number and description finalised for printing.	
May or Nov		New MBS item number appears on Schedule.	
Month 21			Oct/April: Application deadline for listing on Feb/August Prostheses List.
Month 22			Nov/May: Australian Register of Therapeutic Goods/MBS deadline.
Month 23–24			Review of applications by Clinical Advisory Groups. Benefits Negotiation Group negotiation of benefits with suppliers. Approval of benefits by PDC and minister.
Month 25			Feb/August: Product listed on Prostheses List.
Total time	**2 months (but may be up to 8 months)**	**11–21 months: Average 15 months to complete from application submission to final MSAC consideration + 3 months for MBS listing.**	**5 months + additional 6 months if PDC deadline missed.**

Attachment 2

HEALTH TECHNOLOGY ASSESSMENT AGENCIES AND COMMITTEES IN AUSTRALIA FOR MEDICAL PROCEDURES AND DEVICES AND PROSTHESES



Source: Adapted from Productivity Commission 2005, Impacts of Advances in Medical Technology in Australia, Research Report, Melbourne, Fig. 8.2.