Senate Finance & Public Administration References Committee Inquiry: *Government's administration of the Pharmaceutical Benefits Scheme (PBS)*

SUBMISSION

July 2011

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.

Table of Contents

OUR CREDO **2**

1. SUBMISSION INFORMATION **4**

2. INTRODUCTION **5**

3. EXECUTIVE SUMMARY **6**

4. RECOMMENDATIONS **7**

5. BACKGROUND **8**

6. RESPONSE TO TERMS OF REFERENCE **9**

7. CONCLUSION **17**

1. Submission Information

Organisation: Janssen-Cilag Pty Limited

Type of Organisation: Proprietary Limited Company

Address: 1 – 5 Khartoum Road, Macquarie Park NSW 2113

Email and phone contact: Deborah Chan
Corporate & Government Affairs Manager
Ph: +61 2 8875 3395
Fax: +61 2 8875 3286
Email: dchan4@its.jnj.com

Declaration of Interest:

Janssen is engaged in business located in Australia and is the sponsor of a number of medicines listed on the Pharmaceutical Benefits Schedule, including biological medicines.

2. Introduction

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…

Our Credo

As reflected in our Credo, Janssen believes its first responsibility is to patients who use our products and services. Ensuring continued research and development of, and sound community access to, safe, efficacious and cost effective new medicines is fundamental to this.

In order to continue to develop new and innovative medicines, companies such as Janssen seek strong, clear and effective regulatory and reimbursement systems.

We therefore welcome the opportunity to contribute to the Senate Finance and Public Administration References Committee's Inquiry into the Government's administration of the Pharmaceutical Benefits Scheme (PBS).

In this submission, we respond broadly to the Terms of Reference and draw on our company's experience with the deferral of PBS listing of INVEGA SUSTENNA® (paliperidone palmitate), a long-acting injectable antipsychotic, indicated for the acute and maintenance treatment of schizophrenia in adults.

We have not raised every issue related to the PBS that concerns us. It is not feasible to do so and other submissions will address further issues. We also note and broadly support the submission made by Medicines Australia (MA).

3. Executive Summary

In February 2011, the Australian Government announced that Cabinet would consider the PBS listing of all medicines recommended by the PBAC. At the same time, Cabinet decided to defer the PBS listing of seven medicines and vaccines on the Pharmaceutical Benefits Scheme (PBS) until the Federal Budget returns to surplus in 2012-13.

This action signalled a significant revision of the long-standing and well-understood PBS listing process without consultation with affected stakeholders including patients, clinicians, individual companies and the Australian medicines industry.

Before February 2011, medicines estimated to cost $10million per annum or more over the forward estimates, and recommended for listing by the PBAC, would be referred for approval to the Federal Cabinet.

INVEGA SUSTENNA® (paliperidone palmitate), a long-acting injectable antipsychotic indicated for the acute and maintenance treatment of schizophrenia in adults, was recommended by the PBAC for PBS listing in November 2010, with an expected listing date of 1 April 2011. On 25 February 2011, Janssen was informed the PBS listing would be deferred until "circumstances permit".

Janssen understands the Government's desire to return the Budget to surplus. However, listing SUSTENNA on the PBS would add just under $3 million to the PBS in 2011-2012 – about 0.03 percent of PBS expenditure[1] - and just over $3 million in 2012-2013. Janssen believes this cost is modest compared to the value of clinical benefits for patients.

The rationale offered for the deferral of SUSTENNA was that existing (or alternative) treatments are already available, but this is not the case. Currently there are two long-acting atypical antipsychotics listed on the PBS, one of which is heavily under-utilised (less than 1 per cent of prescriptions) due to the three hour post-injection monitoring period required. Thus, the only viable 'alternative' is Janssen's Risperdal CONSTA® and as outlined below, this product has some limitations.

Figures confirmed by the PBAC and Federal Department of Health and Ageing estimate 10,000 Australians would benefit from the PBS listing of SUSTENNA. The key benefit of this medicine is a reduction in the risk of relapse, the main driver for hospital admissions, which account for the majority of schizophrenia costs in Australia.

A recently-commissioned study shows the average cost per schizophrenia relapse to be $27,320. Therefore, if you prevent one relapse using SUSTENNA you've paid for five years of medication. Rather than decreasing costs to Government, the decision to defer the PBS listing of SUSTENNA may

[1]Australian Government Department of Health & Ageing: Australian Health & Ageing System: Concise Expenditure Factbook, June 2011 Edition, Table 1, p2.

in fact increase the cost of the overall health budget and add to the burden on consumers by delaying access to new medicines.

4. Recommendations

Janssen encourages the Senate Committee to recommend that the Government:

1. As a priority, accepts the advice of the PBAC and lists on the PBS the medicines Cabinet deferred in February 2011, including SUSTENNA.

2. Honours the spirit and intent of the 2010 Memorandum of Understanding with the Australian medicines industry.

3. Consults with the medicines industry prior to making decisions that have such significant impacts on consumers, clinicians and the industry.

4. Upholds the principles of the National Medicines Policy regarding the provision of timely and affordable access to medicines.

Janssen would welcome the opportunity to appear before the Senate Committee to provide more information on the issues raised in this submission and to address any questions the Committee may have.

5. Background

5.1 About Janssen

Janssen Australia (Janssen-Cilag Pty Ltd) is a leading international research-based pharmaceutical company, employing more than 340 people across Australia. Part of the Johnson and Johnson Family of Companies, Janssen provides more than 25 prescription medicines in Australia including treatments for cancer, blood disorders, mental illness, Alzheimer's disease, epilepsy, Attention Deficit Hyperactivity Disorder (ADHD), as well as pain relieving medication and oral contraceptive products. Four of Janssen medicines are included in the World Health Organisation's Essential Drug list.

Janssen is a world leader in the research and development of medicines in mental health, with a focus on schizophrenia. Since the 1950s, Janssen has invested in developing long-acting antipsychotic treatments that encourage adherence, reduce relapse and help people live productive lives in the community. From 2005-2010, Janssen invested $13 million in mental health research in Australia including clinical trials, investigator initiated studies, observational trials and registries.

5.2 Janssen's interest in this Senate Inquiry

As a provider of prescription medicines, Janssen regularly engages in the public policy and regulatory approvals processes of the Federal Government. We have done so in good faith since our establishment in 1988, working with successive governments as laws, policies, legislation and regulations have changed and evolved.

Janssen has 25 products listed on the Pharmaceutical Benefits Scheme (PBS) and we are familiar with the need to present an evidence-based case to the Pharmaceutical Benefits Advisory Committee (PBAC), setting out the cost-effectiveness and efficacy of a proposed new medicine. We believe the Government's recent decision threatens to undermine the independence of the PBS listing process and has negative consequences for consumers, clinicians and suppliers of medicines.

6. Response to Terms of Reference

The Government's administration of the PBS with particular reference to:

A: the deferral of listing medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee (PBAC)

Janssen Australia is deeply disappointed with the Government's decision to defer the PBS listing of selected new medicines and refer all medicines recommended by the PBAC to Cabinet. We believe this decision undermines the commitments made by the Australian Government in the Memorandum of Understanding (MoU) and threatens the independence of the PBS listing process.

The PBAC is an independent statutory committee which makes recommendations to the Health Minister about which medicines should be subsidised under the PBS. Applications for listing are assessed on their clinical benefit and cost-effectiveness compared with other medicines available for the same condition or use. Consistent with Australia's universal health care system, the PBS subsidises the costs of prescription medicines to ensure Australians have ready and affordable access to essential medicines.

The PBS also forms a key part of the Australian Government's broader *National Medicines Policy*, which aims to maintain the health of the community in a way that is cost effective and provides appropriate returns to the local industry for the supply of new medicines. The PBS is so highly regarded internationally that it is used by the World Health Organisation for ensuring equity of access to necessary drugs.

Australia's pharmaceutical market entry process has a global reputation as being rigorous and independent and while from time-to-time the industry might disagree with some of the outcomes, by and large, the process is well understood, the rules of engagement are clear and the process is transparent. This changed in February when the Minister announced an unexpected decision to refer all new medicines recommended by the PBAC to Cabinet and defer the listing of selected medications.

The ambiguity surrounding the PBS listing process now that medicines can be deferred indefinitely has created significant uncertainty and confusion for the pharmaceutical industry. Like any business, predictability is essential to continue to develop and introduce innovative medicines in Australia. Comparatively speaking, Australia is a small market for global pharmaceutical companies and domestic subsidiaries often have to negotiate for inclusion in global market access plans. Key to this is the ability to demonstrate predictability within the political, policy and regulatory environment, without which, major industry players will simply switch their investment focus to other economies. This has significant flow-on effects for investment, jobs and importantly, access to medicines for Australians.

Term of Reference B: any consequences for patients of such deferrals

Australian health consumers have a strong awareness of and interest in the PBS and play an active role in advocating for access to new medicines. Consumers closely follow developments in other markets regarding new treatment options for serious illnesses and often advocate for new treatment options to be made available in Australia.

When the PBAC makes a positive recommendation for new treatment options, it gives consumers and carers a new sense of hope. Conversely, the Government's decision to defer the PBS listing of selected new medicines only increases the burden on consumers and carers.

About SUSTENNA

Local and international schizophrenia treatment guidelines confirm the clinical need for multiple antipsychotic treatment options for schizophrenia, such that "In all cases, treatment should be carefully tailored to the unique needs of the individual" (Therapeutic Guidelines 2008, Principles of Treatment, pg 1).

Janssen is concerned the Government appears to have made assumptions about clinical similarities between medicines currently subsidised on the PBS and SUSTENNA. While antipsychotic medications, such as Janssen's RISPERDAL CONSTA®, provide similar benefits to patients at a population level, they are not interchangeable with SUSTENNA on an individual patient basis.

It is well documented that people living with schizophrenia who don't respond to one drug, may respond to another. Similarly, patients who experience adverse effects with one antipsychotic may not experience those effects with a different medication. These factors are taken into consideration by physicians when deciding which long-acting injectable therapies are most suitable for an individual patient.

ToR B (*continued*): any consequences for patients of such deferrals

What's different about SUSTENNA?

(i) Rapid onset of efficacy in acute schizophrenia

Unlike other long-acting injectables, SUSTENNA can be used in the acute patient setting (mental health facility/hospital) as symptom improvement and therapeutic plasma levels are achieved within just 1 week of initiation (compared to six weeks with CONSTA), without the need for lengthy use of oral antipsychotic supplementation during or prior to initiation.

(ii) Route and frequency of administration

SUSTENNA is a once-monthly injection, compared to the typical two week administration required for other long-acting injectable therapies. In schizophrenia, ensuring individuals remain adherent to treatment is not just a matter of convenience. The clinical consequences of missing a dose are relapse and re-hospitalisation. SUSTENNA is a particularly useful option for patients who are:

- Struggling to attend frequent outpatient clinic appointments for administration of their two-weekly injection e.g. where patients are too unwell to travel (still suffering acute symptoms), or are too disorganised or lacking carer support, or those with a history of not 'showing up' for their appointments (i.e. non-adherence);
- Being treated in rural and regional areas where community mental health staff must frequently travel long distances to administer two-weekly injections in a patient's home; and,
- Experiencing frequent deep intramuscular injection pain which is causing undue distress or non-adherence.

(iii) Other key benefits

Other key benefits of SUSTENNA not offered by other long-acting injectables include:

- No requirement for 3-hour post-injection safety monitoring;
- Fewer side effects: SUSTENNA is not associated with sedation, delirium and significant weight gain. However, like other anti-psychotics, it can produce extrapyramidal symptoms (EPS) such as the inability to initiate movement and the inability to remain motionless.
- SUSTENNA can be administered at either deltoid (upper arm) or gluteal (buttock) injection sites. Some long-acting injectables cannot be administered in the upper arm.

Term of Reference C: any consequences for the pharmaceutical sector of such deferrals

Cabinet's decision to defer the PBS listing of selected products has significantly impacted Janssen. It may also have a direct impact on the willingness of multi-national health care companies to invest in the Australian market.

A previously rigorous and transparent process has been complicated by overt Cabinet intervention. There is no clarity on how or when the deferred items will be listed on the PBS. There is confusion on how medicines recommended for listing will be managed prior to the Budget returning to surplus. Finally, there has been no indication of how the Government will address the fiscal impact of listing a backlog of PBAC-recommended medicines once the Budget returns to surplus.

Ultimately, the pharmaceutical industry is no different to other businesses operating in a highly regulated environment. It requires predictability and confidence that the policy levers will not arbitrarily change in order to continue operating effectively. As domestic subsidiaries of international businesses, Australian-based pharmaceutical companies must be able to demonstrate to their global leaders that the regulatory and reimbursement environment is predictable and suitable for investment.

Janssen has several new medicines in its pipeline for which there is a high clinical need. However, the current lack of predictability in Australia's reimbursement system is likely to affect the priority given to introducing new medicines in Australia compared with other nations.

ToR C (*continued*): any consequences for the pharmaceutical sector of such deferrals

About SUSTENNA

Janssen believes our first responsibility is to patients, doctors, nurses and all those who use our products. We are first and foremost concerned with how the Government's decision to defer the PBS listing of SUSTENNA will affect Australians living with schizophrenia, their loved ones and treating clinicians.

Having said this, the Government's decision significantly impacts Janssen's business. Based on an expected PBS listing date of 1 April 2011, Janssen invested significant and important resources in the introduction of this new medicine, including:

- Three clinical programs, including two Australian clinical trials. Medical scientific liaison officers were employed to assist clinicians enrolled in the programs;
- We have employed a team of mental health nurses to train health care professionals in proper injection technique to minimise injection pain;
- Our business has invested significantly in educating health care professionals on the correct dosing regimen, suitable patient profiles and possible adverse events and side effects;
- Significant cost of supplies (or stock) sourced in anticipation of an expected 1 April 2011 PBS listing, lost sales and cost of staff employed specifically to support PBS listing (as described above); and,
- To ensure consumers can access SUSTENNA in public hospitals, Janssen prepared and submitted more than 70 submissions to individual hospital Drug Therapeutic Committees (DTC) across the States and Territories.

Based on these and supporting activities, we estimate Janssen's local investment in SUSTENNA to be in excess of $12 million. This excludes the significant drug development costs incurred, including research and development.

These significant impacts cannot be ignored. The deferral decision has prompted Janssen to review its commitment to clinical programs and other activities planned to support the introduction of new medicines in our pipeline.

Term of Reference D: any impacts on the future availability of medicines in the Australian market due to such deferrals

The deferral decision will force multi-national healthcare companies to recalibrate their plans for listing new medicines on the PBS. As outlined in our response to Term of Reference C, Janssen has several new medicines it is considering for PBS listings over the next few years however, the uncertainty created by the deferrals, and the lack of information on how the listing process will operate when the Budget returns to surplus, greatly jeopardises their introduction to Australia. The regulatory uncertainty created by the deferral decision makes it more difficult for local affiliates to attract global investment from their head offices to register and list medicines in Australia.

Term of Reference E: the criteria and advice used to determine medicines to be deferred

Janssen Australia has been operating in Australia for many decades, and over this period has listed approximately 25 medicines on the PBS. On occasion, Janssen has been unsuccessful in its efforts to list medicines but the reasons were always made clear and the process was transparent and independent.

By contrast, February's deferral decision was made despite the recommendations of the Government's own independent clinical and health economics experts. The brief explanation provided is that there are alternative medicines available. Janssen does not agree with this position and provides evidence in support of this view in our response to Term of Reference B. The criteria and advice used to determine the medicines to be deferred has not been made public. However, considering the clear distinctions between SUSTENNA and other PBS listed long-acting injectables (as outlined earlier) we can only assume this advice was incomplete.

Term of Reference F: the financial impact on the Commonwealth Budget of deferring the listing of medicines

Janssen is unable to comment on the costs of other medicines deferred by the Government. However, it would appear that only minimal savings will be achieved by deferring listings between February 2011 to the 2012-13 financial year (when the budget is expected to return to surplus). In a health budget of **$72.6 billion** in 2011-12, this represents a minor saving at best.

About SUSTENNA

Listing SUSTENNA on the PBS would have a minimal impact on the Commonwealth Budget prior to its return to surplus. Janssen's estimate at January 2011 was that SUSTENNA would add just under $3 million to the PBS in 2011-2012 – the equivalent of **0.03 per cent of current PBS expenditure** - and just over $3 million in 2012-2013.

When seeking listing for a new medicine on the PBS, the sponsor company is required to provide the PBAC with annual cost estimates of the medicine on the Commonwealth Budget over the first five years of listing. The estimated peak annual cost of SUSTENNA is less than $5 million which should be considered in the context of the pre-2011 Cabinet threshold, when new medicines recommended by the PBAC that cost less than $10 million/year over the forward estimates did not require Cabinet approval.

A recent Janssen-commissioned Deloitte Access Economics report looked at the cost of relapse in schizophrenia and the potential cost savings through increased use of long-acting injections. The April 2011 report found the number of relapses in Australians living with schizophrenia to be about 25,571 over a year in 2009-2010. The report estimated the total cost of relapse to be $698.6million and the average cost per relapse is estimated at $27,320 (Direct costs - $19,080; indirect costs - $8,240).

Poor adherence to medication (particularly oral formulations) is the single greatest barrier to the effective management of schizophrenia and a key driver of relapse. The Deloitte Access Economics' report shows preventing one relapse using SUSTENNA pays for five years of treatment.

The report estimated that if prescriptions of long-acting injections (such as SUSTENNA) were to increase from 17% to 30% in Australia (as in the US and UK), and all those switched were non-adherent to oral antipsychotics, the avoided cost of relapse would be approximately $52.5 million per year.

Term of Reference G: the consultation process prior to a deferral

Janssen was not consulted in advance of the Government's decision to defer the PBS listing of SUSTENNA. The PBAC recommended the medicine be listed on the PBS at its November 2010 meeting and Janssen subsequently worked with the Department of Health and Ageing in relation to price. Janssen was informed on the day the deferral was announced, just over a month from the expected date of listing. No information was provided as to the criteria or approach used to determine which medicines were deferred and which were listed, nor were any details given as to how the PBAC process would work moving forward and how deferred medicines would be considered in that context.

Term of Reference H: compliance with the intent of the Memorandum of Understanding signed with Medicines Australia in May 2010

While Janssen understands the Australian Government's desire to return the Budget to surplus in 2012-13, we believe the deferral is a breach of the spirit and intent of the Memorandum of Understanding (MoU) reached between the Government and Medicines Australia on 6 May 2010. When Minister Roxon introduced the MoU legislation into Parliament in 2010, the agreement was said to embody '*an historic level of cooperation and collaboration between government and the pharmaceutical industry*'[2].

While the deferral decision may deliver short term budgetary savings, it undermines the trust and cooperation engendered by the MoU. In Janssen's opinion, this decision is not consistent with Clause 29 in the MoU, which requires the Commonwealth to '*use its best endeavours to implement a maximum timeframe of six months for consideration and decision by Cabinet*'. While one may technically argue that a deferral is a 'decision', Janssen does not believe a deferral is a 'decision' within the spirit and intent of the MoU, as it has created significant uncertainty for the business, consumers and clinicians.

As Minister Roxon indicated in Parliament, the reform was designed to deliver PBS savings of $1.9 billion while ensuring access to medicines and providing a more predictable policy environment for the pharmaceutical industry. However, just over six months later the industry found the Government had changed the rules with the decision to refer all recommended new listings to Cabinet for approval, rather than those with a peak annual cost of $10 million.

[2] Roxon, N (2010): Second Reading speech, National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010, 29 September.

Term of Reference I: Any other related matter

Consequences for Clinicians

The potential consequences for clinicians of such deferrals is not addressed in the Inquiry's Terms of Reference however, Janssen believes it is an issue that warrants examination by the Committee due to the potential impacts on patient health outcomes.

About SUSTENNA

SUSTENNA provides benefits to clinicians in their treatment of patients with schizophrenia. Unlike other similar treatments:

- patients do not require post-injection monitoring (with some treatments, patients must be monitored for up to three hours for post-injection sedation/delirium syndrome)
- reduction in delivery frequency presents significant time and cost savings to public health services
- the medicine does not require refrigeration
- the medicine does not require reconstitution
- patients do not need oral supplementation with other medication
- there is a choice between deltoid (upper arm) and gluteal (buttock) injection sites

7. Conclusion

Janssen would like to thank the Committee for the opportunity to make a submission to the Inquiry.

Over the past 23 years Janssen has demonstrated a deep and sustained commitment to the health of our nation by providing Australians with safe, efficacious and cost effective new medicines under the PBS. However, in order for Janssen and the medicines industry to continue developing new medicines for Australians, we require predictable, transparent and effective regulatory and reimbursement systems.

Janssen would welcome the opportunity to appear before the Committee to provide more information on the issues raised in this submission and to address any questions the Committee may have.