



***PRODUCTIVITY COMMISSION***

**MENTAL HEALTH INQUIRY**

**SUBMISSION**

**April 2019**

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## **Our Credo**

We believe our first responsibility is to the patients, doctors and nurses, 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 provide value, reduce our costs and maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit.

We are responsible to our employees who work with us throughout the world. We must provide an inclusive work environment where each person must be considered as an individual. We must respect their diversity and dignity and recognize their merit. They must have a sense of security, fulfillment and purpose in their jobs. Compensation must be fair and adequate and working conditions clean, orderly and safe. We must support the health and well-being of our employees and help them fulfill their family and other personal 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 highly capable leaders 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 help people be healthier by supporting better access and care in more places around the world. We must be good citizens – support good works and charities, better health and education, and bear our fair share of taxes. 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, investments made for the future 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.

## Submission Information & Company Overview

<b>Organisation:</b>	Johnson & Johnson Pty Ltd
<b>Type of Organisation:</b>	Proprietary Limited Company
<b>Address:</b>	1 – 5 Khartoum Road, Macquarie Park NSW 2113
<b>Email and phone contact:</b>	Stuart Englund Senior Manager, Corporate & Government Affairs Janssen Australia (Janssen-Cilag Pty Ltd) +61 2 9815 3298 / senglun@its.jnj.com

Johnson & Johnson Pty Ltd is a subsidiary of Johnson & Johnson, the world’s most comprehensive and broadly-based healthcare company. In Australia we provide products and services including medical devices, diagnostics, pharmaceuticals and consumer healthcare products.

The Johnson & Johnson Family of Companies in Australia consists of:

- Johnson & Johnson Pacific Pty Limited – consumer health brands;
- Johnson & Johnson Medical Pty Limited – medical devices and related technology; and
- Janssen-Cilag Pty Limited – pharmaceuticals.

We employ approximately 1,500 Australians who bring innovative ideas, products and services to advance the health and well-being of the patients we serve. We recognise the impact of serious conditions on people’s lives, and we aim to empower people through disease awareness, education and access to quality care. Our research and development focus on identifying medical needs and harnessing the best science, whether from our own laboratories or through strategic relationships and collaborations.

**Johnson & Johnson Pacific** is a provider of consumer health and wellbeing products, offering families more than 650 trusted solutions for their most common health and wellbeing needs. Many of our brands have earned consumers’ trust over generations.

**Johnson & Johnson Medical** produces a range of innovative products and solutions used primarily by healthcare professionals in the fields of orthopaedics, neurological disease, vision care, diabetes, infection prevention, diagnostics, cardiovascular disease, and aesthetics. We are the largest medical technology provider in Australia working across public and private sectors.

**Janssen** is creating a future where disease is a thing of the past. We’re the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Neuroscience, Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Oncology, and Pulmonary Hypertension.

## Submission

Johnson & Johnson, through its pharmaceutical companies represented in Australia by Janssen, has a long history of working to provide medicines to help support mental health. In the 1950's Janssen's founder, Dr Paul Janssen, developed haloperidol then a new treatment for schizophrenia. Since then Janssen has continued to invest in, discover and develop new medicines for mental health.

In 2016 more than 17,000 patients in Australia prescribed Janssen mental health products<sup>1</sup>. Our research and development program includes a strong focus on new medicines seeking to treat schizophrenia, major depressive disorder, treatment resistant depression and suicidal ideation. We also provide medicines for a much wider range of chronic and acute conditions that, while not mental illnesses themselves, have a significant psychosocial impact due to stigma, social isolation, emotional distress and/or stress on relationships.

Our experience in supporting mental health goes significantly beyond medicine and we recognise that managing the physiological impact of disease is only part of the answer. As part of our activities we invest in patient programs that help connect patients with support that will ultimately lead to measurable, improved outcomes.

We have a long history of working closely with a wide range of patient, carer and health care professional organisations working in the mental health sector to support better outcomes.

There are a number of additional obstacles that impact on the access to new medicines for mental health issues that arise from Australia's current medicines evaluation processes.

We work with patients, health care practitioners, patient organisations, health care bodies, researchers and governments to help provide access to our current medicines, overcome the barriers to doing so and to continue the work of researching and developing new medicines.

### **Our experience in providing medicines in Australia**

#### *Schizophrenia*

Janssen has a long history of researching, developing and providing access to innovative medicines to help treat schizophrenia. We recognise that patients need access to a range of support in order to make and maintain recovery including: psychological therapy, social support and clinical care, including medication.

Depending on a patient's circumstances the frequency of relapse from recovery can be high<sup>2</sup>. A significant predictor of relapse is non-adherence<sup>2</sup>. There are many reasons for non-persistence including inadequate discharge planning<sup>3</sup>.

The impact of relapse can be significant. Previous research in this area indicates that there is a measurable, significant cost to relapse: arising from such elements as the increased use of health resources and the impact of a patient's workforce participation. An estimate of the total cost in Australia of relapse in people with schizophrenia was estimated to be \$698.6 million over a 12-month period in 2009-10<sup>4</sup>. This includes \$210 million in indirect costs such as lost productivity due to unemployment and premature mortality<sup>4</sup>.

*ATLAS – improving existing support to the patient*

In recognition of this impact Janssen is currently working with health services to provide ATLAS, a structured program designed to help people living with schizophrenia transition from community mental health services to primary care. ATLAS connects community mental health and general practice to help them work together efficiently.

This program, which is available to those being treated with Janssen long-acting therapies, was developed following feedback from psychiatrists, GPs, consumers and carers. It aims to support patients in their transition from Community Mental Health (CMH) Centers into GP care, by overcoming barriers to treatment. The key features are an online clinician dashboard and system of alerts, GP appointment reminders (SMS or phone call), nominated support person follow-up, access to a mental health nurse and a pharmacy dispense and delivery service.

Janssen is currently undertaking an assessment of the impact of the program and initial results indicate that the ATLAS program assists with both patient adherence and persistence to treatment. With these support services, the majority of treatment appointments are attended on time, and patient persistence on long-acting treatment exceeds the overall Australian treatment persistence rate<sup>5</sup>. This relatively simple 'beyond-the-pill' program helps extend the effectiveness of a treatment that is already cost effective.

*The broader impact of disease on mental health*

In addition to medicines for mental health issues Janssen provide medicines for a wide range of chronic and acute conditions, including autoimmune conditions, cancers and communicable diseases. While not mental illnesses themselves, many of these conditions have a significant psychosocial impact due to stigma, social isolation, emotional distress and/or stress on relationships. Effective treatment can help address these impacts.

Psoriasis is a systemic auto-immune disease that when severe, is painful and disabling. It is driven by an overactive immune system which causes skin cells to grow too quickly, resulting in thick, red, scaly lesions on the skin, known as plaques, which can occur anywhere on the body<sup>5, 6, 7</sup>. Although estimates vary, it's thought approximately 450,000<sup>5</sup> Australians are living with psoriasis, out of which 80% have plaque psoriasis<sup>6</sup>. The condition usually starts in young adults

with 75% of affected people developing psoriasis before the age of 45 years<sup>7</sup>. According to the Australasian Psoriasis Registry, out of more than 1,500 patients 16% have depression<sup>8</sup>. Those living with psoriasis may not only suffer depression from the stigma associated with visible skin lesions<sup>9</sup> but many also experience frustration from a lack of successful treatments<sup>10</sup>.

One in four people with arthritis experiences mental health issues<sup>11</sup>. People with mental health conditions are also around 50% more likely to have arthritis than the general population<sup>12</sup>.

### **Seeking to address unmet need in mental health**

Janssen is currently developing medicines focused on major depressive disorder, treatment resistant depression and suicidal ideation. These medicines may help address significant unmet need for patients living with mental illness.

More than 1.3 million people live with depression, that is 5.9% of the national population<sup>13</sup>. Major Depressive Disorder (MDD) can be a debilitating illness<sup>14</sup>. Up to 30% of patients with MDD do not respond to traditional antidepressant medications<sup>15</sup>. Only 1 in 3 of patients achieve remission after their first antidepressant treatment<sup>16</sup>. As many as 2 in 3 of patients do not fully recover while on antidepressant treatment<sup>15</sup>. The proportion of MDD patients who achieve remission decreases significantly after each treatment failure, from 31% with a second treatment, to 14% with a third and 13% with a fourth<sup>16</sup>. MDD patients are at a 20-fold greater risk of suicide than the general population<sup>17</sup>, and a delay in finding an effective treatment may prove life-threatening<sup>18</sup>. Patients with treatment resistant depression (TRD) have significantly higher rates of comorbidities<sup>19</sup> and 30% of TRD patients attempt suicide at least once during their lifetime<sup>20</sup>. TRD patients have a 7-fold increase in suicide attempt or self-inflicted injury, compared with non-TRD MDD<sup>21</sup>.

Currently available medicines take a long time to show effectiveness and are often ineffective<sup>22</sup>.

These medicines have administration and monitoring requirements not currently provided for in the Australian healthcare setting. There is no current model of care yet established and questions of how care coordination will be funded and established across different settings including in public and private hospitals, ambulatory care settings and the primary health setting will need to be addressed as part of any provision of access to them.

### **Access to new medicines – systemic issues**

There are two additional obstacles that may impact on the access to new medicines for mental health issues that arise from Australia's current medicines evaluation processes: the differential criteria used to assess medicines versus other medicines, including differential valuations of life years; and the current practice of assessing the value of new medicines by reference to existing medicines which are subject to ongoing price discounting.

Janssen medicines available in Australia, where reimbursed by the Australian Government via the Pharmaceutical Benefits Scheme (PBS), are subject to, arguably, the most rigorous evaluation of the cost-effectiveness of any government procurement process. This process is conducted by the Pharmaceutical Benefits Advisory Committee (PBAC).

In this Inquiry the Productivity Commission will look at the effects of supporting mental health on economic and social participation, productivity and the Australian economy. The PBAC, when assessing the benefits of medicines, works with guidelines that specifically exclude consideration of the economic and social benefits when assessing the value of medicines. The PBAC guidelines restrict the focus of benefits to a health system perspective (the avoidance of costs and benefits within the health system only). This narrower focus means that wider benefits that the Productivity Commission would like to consider are not taken into account when deciding whether or not to subsidise a medicine through the PBS.

In addition to this, the threshold used by the PBAC to decide on medicines funding, while not explicitly, has been estimated to be about \$50,000 - \$76,000 per incremental quality adjusted life year gained<sup>23</sup> generally and potentially less for mental health medicines. There does not appear to be any annual indexation of this limit. However, the value of a statistical life-year used by the Australian government was assessed to be \$182,000 in 2014 dollars, a much higher figure<sup>24</sup>. This suggests an inconsistency in relation to other branches of government.

In assessing the cost effectiveness of a new medicine, the PBAC compares the price of a new medicine to the price of existing medicines. The price of the existing medicine will have been previously assessed by the PBAC in that medicine's application for PBS listing. However, the price of the existing medicine will not have been adjusted for any inflationary impacts that may have occurred since listing and may have been subject to mandatory discounting via the reference price policy or the accelerated PBS Price Disclosure process. It may also have been subject to the statutory price discount on the introduction of a generic competitor. The combined impact of these various effects is that the new medicine may not be compared to the original price of the existing medicine and certainly not any inflation adjusted price. This process is referred to as comparator erosion.

The impact of this process can be seen in the failure of new antidepressants medicines such as vortioxetine, agomelatine, and the adjunctive use of quetiapine SR to treat depression to gain a listing at a reasonable price (e.g. see PBAC Public Summary Documents in relation to: vortioxetine, agomelatine and quetiapine SR). Lower prices are good for consumers, but they have had a secondary impact on the PBS availability of new medicines to treat mental health issues.

For an example of the price decreases seen in mental health medicines, the following table shows the decline in nominal prices for typical antidepressants. All these values are the dispensed price for max quantity from the PBS Schedules, excluding brand price premiums as these are not allowed for new listings.

<b>Decline in Nominal Prices for Typical Antidepressants</b>	
1.	Fluoxetine 20mg: Mar 2019: \$15.04 / Mar 2014 price: \$15.70 / Mar 2009 price: \$20.38 / Feb 2004 price: \$34.06.
2.	Sertraline 100mg: Mar 2019 price: \$13.02 / Mar 2014 price: \$12.48 / Mar 2009 price: \$24.23 / Feb 2004 price: \$36.87.
3.	Venlafaxine 150mg: Mar 2019 price: \$15.72 / Mar 2014 price:\$29.64 / Mar 2009 price: \$52.19 / Feb 2004 price: \$52.06.
4.	Quetiapine SR 150mg Mar 2019 price: \$27.85 / Mar 2014 price: \$86.91 / Mar 2009 price: \$196.14 / Feb 2004 price: \$201.15.
Source: <a href="http://www.pbs.gov.au/info/publication/schedule/archive">http://www.pbs.gov.au/info/publication/schedule/archive</a> Accessed April 2019.	

Janssen remains committed to the research and development of new medicines in mental health, as noted above, however, our recent experience of the broader trends in the sector is that there is a decline in the focus on mental health in the investigation of new medicines. While investigation into new medicines in the broader category of neurological diseases continues it would appear that the substantial portion of this investigation is in neurodegenerative conditions (e.g. Alzheimer’s Disease).

**Improving existing support to patients & finding new ways**

We are working with patients, health care practitioners, patient organisations, health care bodies, researchers and governments to address these issues and help provide access to our current medicines and to continue the work of researching and developing new ones. We will continue to provide our expertise, our insights, educate and to support to help ensure that we address the needs of those Australians living with mental health issues. Medicines are only part of the solution to those challenges and we will work to integrate other solutions into treatment models. We will continue to provide medicines that have proved effective, developing new ones to address unmet need, developing programs help make the delivery of current medicines more effective and working to address health system issues that can be a barrier to access.

## Endnotes

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