



*Johnson & Johnson  
Family of Companies in Australia*

Submission to the  
Transparency Review of the  
Therapeutic Goods Administration

11 February 2011

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## 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 recognise 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. Executive Summary

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**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 regulated by the Therapeutic Goods Administration (TGA), and industry contributions fund 100% of TGA's regulatory activities.

**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 fifth-largest biologics company
- And the world's seventh-largest pharmaceuticals company.

We have more than 250 operating companies in 57 countries employing 119,400 people.

In 2010 we invested over US\$7.50 billion in research & development.

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 1,500 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; Johnson & Johnson Pacific; 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 and GDP of \$366 million.

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*

Janssen-Cilag Pty Ltd (Janssen) is a research-based company that markets pharmaceuticals for a range of conditions including those 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.

### *Tasmanian Alkaloids*

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

In 1995, Tasmanian Alkaloids 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 healthcare system through both the supply 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 assistance to local doctors. It is focused on a broad range of medical products through a number of separate groups: Ethicon women's health and urology; wound closure and wound management; advanced sterilisation; Ethicon Endo-Surgery minimally invasive technology, laparoscopic instruments and mechanical staplers; 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 of its business franchises; from involvement in global programs and first-in-human studies of new innovative technologies, to support for 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 (e.g. 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 and in the top thirty suppliers of manufactured goods to grocery supermarkets. JJP is committed to providing the best service, programs and advice to consumers, healthcare professionals and the community, and is dedicated to bringing to market innovative healthcare solutions.

JJP's broad product range spans the 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. Comments on the TGA Transparency Review

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**

Our ambition is to ensure the continued health and well-being of all members of the Australian community. As supported by our Credo, we believe that doctors, nurses and patients, mothers and fathers and all others who use our products and services should have access to relevant information about the therapeutic goods that they are using or intend to use. We therefore welcome this opportunity to contribute to the review of TGA transparency.

We have noted and broadly support the meeting papers brought to the 7 Dec 2010 meeting of the Transparency Review Panel (available at <http://www.tga.gov.au/consult/tga-transparency-review-panel-01.htm>, accessed 9 Feb 2011) by the industry associations that members of the Johnson & Johnson Family of Companies contribute to: Medicines Australia; Medical Technology Association of Australia; and Australian Self-Medication Industry.

We also note and generally support the meeting papers brought to the meeting by panel members. We particularly note the contribution from the NSW Clinical Excellence Commission, Professor Cliff Hughes AO, as containing a great deal of wisdom and insight into this issue.

The transparency panel needs to consider different classes of information, which may be loosely defined as data, information, knowledge and wisdom. The TGA currently provides a lot of data publically (e.g. the entries on the Australian Register of Therapeutic Goods) but possibly the needs are for information, knowledge and wisdom. In prescription medicines, TGA has (relatively recently) started providing information (e.g. Product Information, Consumer Medicine Information, Australia Public Assessment Reports). These information activities should be assessed and feedback sought on these transparency initiatives.

Knowledge provided to the public by Health Canada and the European Medicines Agency around the approvals of new medicines are worth examining, particularly if feedback is available on the success of these implementations. We also note the US Food and Drug Administration's extensive transparency initiative.

However, it must be stated that certain information, particularly regarding specific regulatory applications should be accepted and identified as commercial in confidence and there must be confidence that this information should not be publically disclosed. We note the TGA's statement in their meeting paper that the FDA publishes details of all products received for evaluation and respectfully submit that this is not the case.

We do believe that it is appropriate for the TGA to provide greater openness on OTC evaluation times for the different types of regulatory submissions it manages to aid transparency and effective project planning.

As industry funds 100% of the costs of TGA's regulatory activities, we are also interested in effective and cost-effective initiatives that increase transparency where it is most needed and we believe this will improve public confidence in the health care system at large.

## **4. Conclusion**

Thank you again for the opportunity to submit.

We trust this feedback will be useful to the Review Panel.

The Johnson & Johnson Family of Companies in Australia would be pleased to assist the Review Panel 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; and
4. otherwise contribute to the Transparency Review of the TGA.