



FAMILY OF COMPANIES

**Submission to the Data Availability  
and Use Public Inquiry**

**29 July 2016**

## **Contents**

Our Credo .....	3
Submission information & company overview .....	4
Executive Summary & recommendations.....	6
Characteristics of high a value data set .....	8
Community benefits from increased availability .....	9
Examples of government initiatives.....	10
How governments could more effectively utilise data.....	12

## 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 fulfil 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 realise 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>	Mr Mustafa Acar Outcomes Research Project Manager Janssen-Cilag Pty Ltd, The Johnson & Johnson Family of Companies in Australia

### Declaration of Interest:

Johnson & Johnson Pty Ltd (JJPL) a wholly owned subsidiary of Johnson & Johnson (J&J). J&J is the world's most comprehensive and broadly based healthcare company. JJPL is the parent company of three operating company subsidiaries supplying J&J products and services in Australia that can be broadly categorised into three principal areas: pharmaceuticals, medical devices, and consumer healthcare.

The Johnson & Johnson Family of Companies in Australia (JJFC) consists of:

- **Johnson & Johnson Consumer** (Johnson & Johnson Pacific Pty Ltd), known for its portfolio of leading consumer health and beauty products;
- **Johnson & Johnson Medical Devices** (Johnson & Johnson Medical Pty Ltd), a medical devices and technology business;
- **Janssen** (Janssen-Cilag Pty Ltd), the pharmaceutical companies of Johnson & Johnson.

We employ approximately more than 1,500 Australians who are passionate about bringing innovative ideas, products and services to advance the health and well-being of people. Driven by our commitment to patients, we bring innovative products, services and solutions to people throughout the world. 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 strategy focuses on identifying unmet medical needs and harnessing the best science in the world, whether from our own laboratories or through strategic relationships and collaborations.

Johnson & Johnson Consumer is a leading provider of consumer health, wellbeing and beauty products offering families in Australia and New Zealand more than 650 trusted solutions for their most common health and wellbeing needs. Many of our brands are #1 in the categories in which they compete and have earned consumers' trust over generations.

Johnson & Johnson Medical Devices produces a range of innovative products and solutions used primarily by healthcare professionals in the fields of orthopaedics, neurological disease, vision care,

diabetes care, infection prevention, diagnostics, cardiovascular disease, and aesthetics. We are the largest medical technology provider in Australia and work across both the public and private sectors.

The Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Janssen has a long-standing history in making a meaningful difference in global public health, dating back to Dr Paul Janssen's pioneering work in mental health and pain medications, as well as the development of more than 80 medicines, four of which are included on the World Health Organisation's List of Essential Medicines. Inspired by his legacy, we aim to help more people in more places have access to our medicines and to sustainable, effective healthcare solutions.

In summary the JJFC in Australia is driven by a commitment to patients. We develop sustainable, integrated healthcare solutions by working side-by-side with healthcare stakeholders, and investing in partnerships based on trust and transparency. We provide education materials to healthcare professionals throughout the country – from student doctors and nurses through to registrars and consultants. We also have a broad range of products in baby care, skin care, oral care, wound care and women's health, as well as over-the-counter pharmaceutical products.

**JJFC Industry Group Memberships:**

Please find below a list of the relevant industry associations in which our operating companies maintain membership. It should be noted that our operating companies have contributed to submissions by many of the organisations listed.

- ACCORD – an advocate association for the Consumer, Cosmetic, Hygiene & Specialty Products Industry
- API Manufacturers Australia
- Australian Self Medication Industry (ASMI)
- AusBiotech – Australia's Biotechnology Association
- Australian Food & Grocery Council (AFGC)
- Medical Technology Association Australia (MTAA)
- Medicines Australia (MA)

## Executive Summary

J&J are recognised as worldwide leaders in catalysing the demand for, generation and effective use of data. As such, we are seeking partnerships with government, public and private sector organisations and academics to use linked health care data to uncover disease insights, to demonstrate the value of therapies and improve health system delivery.

This submission aims to:

- Discuss the community benefit of improved health data availability;
- Outline the characteristics of high value data sets;
- Show relevant international government initiatives and examples of their impacts;
- Suggest federal and state government bodies take steps to create high value health data.

To summarise the discussion paper, the JJFC suggest that:

1. There is a growing importance of government health data in that it enables health systems leaders, researchers and therapy providers to drive health care innovation. Advancements in technology now allow for the effective collection and linkage of real world data. This holds great promise towards improving the lives of patients by ensuring that they have timely access to the right medicines.
2. Payers of therapies are seeking more predictability and evidence of how treatments work along with their impact on patients in the real world. Linked, accessible and anonymised patient health data can complement randomised clinical trials to strengthen the culture of evidence based decision making.
3. Projects involving health data must meet the highest standard of quality and ethics through robust dialogue, transparency and collaboration between government, academics, providers, manufacturers and payers.
4. There are numerous international examples and research papers that indicate significant community benefit can be derived from linking public data and making it reasonably available.

## Recommendations from the Johnson & Johnson Family of Companies in Australia

1. The government take steps to anonymise and improve the usage of public health data;
2. Patient related health data is made broadly accessible to industry and researchers for answering research questions that will inform system decision making;
3. There is openness across all government bodies to collaborate on mutually beneficial research initiatives that will address system gaps and ultimately lead to health system innovations.

## Introduction

JJFC welcome the review and agree that there are significant opportunities to streamline and simplify requirements and processes in the availability of health related data in Australia. This would in effect lead to an evolution in our understanding of the Australian health landscape, allowing for strategic and evidence based innovation.

Given our businesses have substantial operations across multiple sectors (pharmaceuticals, medical devices and over the counter medicines) we are in an excellent position to contribute to the present discussion around data availability and any future initiatives or actions. Our broad healthcare offering affords us unique perspectives on the inter-relationships of Australian healthcare sectors. In addition we are leading contributors to numerous industry groups which gives us a good understanding of impacts for the wider industry.

We welcome the opportunity to further contribute to this review or subsequent consultations that might result from the recommendations that will be made by the expert panel.

### 1. What characteristics define high-value data sets?

A high value data set, in the Australian health care setting, is one which enables an investigation into the issues today, prediction of future concerns and research into the application of therapies outside of a highly controlled clinical trial setting. The analysis of this high value data set would then allow for the design of appropriately scoped intervention strategies that address issues identified. This would result in an evidence based investment approach to health care innovation.

In order to be able to achieve these sorts of outcomes, data-sets must be **reasonably accessible** with **streamlined approvals**, have safeguards to **protect individual privacy**, are able to be **linked** across various public and private bodies, with **standardised terminology** across the nation in a manner that is **aligned with international standards**.

## 2. What public sector data sets should be considered high value data to the business sector, research sector, academics or the broader community?

The below is a non-exhaustive list of the sorts of data sets the JJFC consider to contain valuable information. Each provides an insight into the Australian health care system. Whilst these are each, on their own, valuable sources of data, if these had the above characteristics of a high value data set, the potential to generate insight would be far greater.

- Patient procedure records (e.g. MBS)
- Prescription records (e.g. PBS)
- Death records (e.g. National Death Index, Hospital Morbidity Database)
- Records relating to illness prevalence, incidence and mortality (AIHW hold a number of these)
- ABS data (i.e. Demographic data relating to geography, age, gender, socioeconomic status, when combined with other data-sets can provide greater health insight)
- Hospital records (patient admission, treatment, diagnosis; The Independent Hospital Pricing Authority)
- GP and specialist data
- Community centre data
- Survey data
- Registry data (e.g. Disease specific, National Joints Registry)
- Pathology and diagnostic imaging
- National Diabetes Service Scheme
- Electronic Health Records
- National Health Performance Agency (Has collected data for a few years and closed effective 30 June 2016)

### **Hypothetical – How high value data could achieve a deeper understanding of the present health care landscape**

Patient treatment statistics can be drawn by analysing Pharmaceutical Benefits Scheme (PBS) data, which provide an indication of purchase rate of therapies that are approved by the Pharmaceutical Benefits Advisory Committee (PBAC), of which a 10% sample is currently available for commercial uses through a number of custodians. Whilst this information is useful (and can be linked with Medicare Benefits Schedule data), we see the opportunity to do more if this data was linked to, for instance, other sources that allowed the examination of health outcomes.

We have identified that limitations arise when, for patient groups, we are unable to deduce pre-treatment indicators that are contributory to a diagnosis (e.g. lifestyle factors); and we are unable to deduce critical post-treatment factors (i.e. outcome of therapy). Both of these factors are crucial in understanding opportunities for early intervention strategies as well as in evaluating the effectiveness of health care treatments outside of random clinical trials. Should the government take steps in establishing high value data, it is feasible this data could be extracted from other sources, connected with the PBS data and enable this important research to take place.



### 3. What benefits would the community derive from increasing the availability and use of public sector data?

At a high level, linked and available data holds great promise towards improving the lives of patients by ensuring that they have timely access to the right treatments. The JJFC are therefore seeking partnerships to use data to derive this potential value and uncover disease insights, demonstrate the value of therapies and improve health system delivery. This opportunity will ultimately advance health care sustainability in Australia.

#### Community Benefits of Available High Quality Health Data

Whilst not an exhaustive list, the below is intended to be an indication of the variety of benefits to the Australian community through the development of a high value data set.

1. In 2014, Lateral Economics estimated that open government data could contribute up to \$25<sup>1</sup> billion per annum to the Australian economy. This analysis also suggests that Australian government held health-specific data alone could account for an increase of \$5.9 billion per annum<sup>2</sup>.
2. The ability to construct local comparisons of health related performance indicators will allow the identification of opportunities for improvement, for example:
  - Uncovering the critical factors impacting real world effectiveness of a therapy or procedure from that observed in a clinical trial setting (either positively or negatively), permitting the design of strategies or solutions to overcome such issues or capitalise on observed improvements.
  - In Sweden, the survival rates of patients who suffer a heart attack (myocardial infarction) were published, which showed performance by hospital tended to vary. Two years following this, the hospitals that had the lowest survival rates improved their processes, resulting in their mortality rate declining by 50%<sup>3</sup>.
3. There will be an improved ability to understand geographic and socioeconomic factors relating to healthcare issues. By assessing the scope of a health care issue (whether it be specific to a locality, region, or the commonwealth as a whole), the derived benefit is that this enables:
  - Identification of health care issues specific to certain communities (e.g. rural or remote).
  - Greater precision and smarter investment into the design and roll-out of intervention strategies.
  - Evaluation of intervention effectiveness.
4. Healthcare decision makers (i.e. PBAC, hospitals, and healthcare practitioners) want to see a broader indication of the outcomes of patient treatments. For example:
  - Sweden has a data rich environment that has allowed a finding demonstrating that the use of an antipsychotic medication for schizophrenics resulted in a 45% reduction in crime

---

<sup>1</sup> Lateral Economics, Open for Business: How Open Data Can Help Achieve the G20 Growth Target, June 2014, p. 23

<sup>2</sup> Lateral Economics, Open for Business: How Open Data Can Help Achieve the G20 Growth Target, June 2014, p. X

<sup>3</sup> Lardsson, S., Lawyer, P. and Silverstein, M. B. (2010), "From Concept to Reality: Putting Value-Based Health Care into Practice in Sweden", The Boston Consulting Group

committed by patients<sup>4</sup>. This finding can be used to supplement the strictly controlled environment of a randomised clinical trial where such benefits may be difficult to capture, contributing to a greater understanding of the community benefits relating to the treatment.

5. Improved ability to compare Australian health issues with those internationally. The derived benefit in this is that it will strengthen our ability to learn from tried and tested solutions that have occurred across the globe.
6. Increased private investment into:
  - Academic partnerships and research into unexplored data sets that generate deeper insight into Australian health care;
  - Health care solutions that cater to community needs, based on evidence
  - Collaborations with hospitals and health districts that help understand the impacts of procedures and treatments outside of highly controlled settings (such as randomised clinical trials).

#### 4. What specific government initiatives (Australian or overseas) have been effective in improving data access and use

Some notable examples of international government initiatives include:

- The Re-Use of Public Sector Information (or, the PSI Directive) is a European Union directive that encourages member states to make as much public sector information available as possible.
- Sweden has taken a number of steps to establish a rich data infrastructure, making it a hotspot for medical research in the way it enables uniquely long term studies.
- In the UK, the Clinical Practice Research Datalink (CPRD) was established as a linkage of anonymised health care data for research purposes, leading to over 1,500 publications using this database. These publications tend to focus on health in the real world. Some examples include:
  - Longitudinal research into paediatric ADHD medication usage, and comparing this internationally<sup>5</sup>,
  - An investigation into lifestyle factors that might contribute to seizure incidents across patients with depression<sup>6</sup> and,
  - An examination into a suggested association between inflammatory bowel disease and cancer malignancy<sup>7</sup>.

---

<sup>4</sup> Fazel, S., Zetterqvist, J., Larsson, H., Lonnstrom, N., Lichtenstein, P. (2014), Antipsychotics, mood stabilisers, and risk of violent crime

<sup>5</sup> Beau-Lejdstrom, R., Douglas, I., Evans, S.J. and Smeeth, L (2016), Latest trends in ADHD drug prescribing patterns in children in the UK: prevalence, incidence and persistence

<sup>6</sup> Bloechliger, M., Ceschi, A., Ruegg, S., Jick, SS., Meier, CR., Bodmer, M. (2016), Lifestyle factors, psychiatric and neurologic comorbidities, and drug use associated with incident seizures among adult patients with depression: a population-based nested case-control study

<sup>7</sup> Wilson, JC., Furlano, RI., Jick, SS., Meier, CR. (2016), A population-based study examining the risk of malignancy in patients diagnosed with inflammatory bowel disease

- “In Canada, administrative data on hospital discharges, prescription drug usage and ambulatory care is linked to population health survey data, birth and death databases and cancer registries.” (Productivity Commission, 2013, p.12)<sup>8</sup>.
- New Zealand is taking steps to improve public sector data available, where the “Minister for Statistics stated that the initiative was part of a ‘Government objective to have all public sector agencies releasing high value public data for re-use’” (Williamson, 2013, cited in Productivity Commission 2013, p.13).

### International Johnson & Johnson Collaborations

The below table demonstrates collaborations Johnson & Johnson have formed across the globe with government and academic bodies, making use of publicly available data. It is suggested that these are inherently exemplary of what results from a high value data set.

<u>Location</u>	<u>Details</u>
Sweden	<ul style="list-style-type: none"> <li>• Johnson &amp; Johnson Innovation, a subsidiary of J&amp;J, has signed an agreement with Karolinska Institutet Holding AB, a wholly owned company of the Karolinska Institute. The Karolinska Institute is an academic organisation funded partly by the European Union and the Swedish government. The collaboration entails ongoing research into various therapeutic areas utilising public data.</li> <li>• This collaboration makes primary use of the data rich infrastructure available in the Nordic region that has resulted from laws that support the re-use of public sector information, and government initiatives that create the platforms for this to occur.</li> </ul>
Hungary	<ul style="list-style-type: none"> <li>• The National Health Insurance Fund (“OEP”) is a national payer in Hungary. Leveraging law on the re-use of public data, Janssen Hungary partnered with this national payer with a mutual interest in research findings, methodology, understanding market and treatment pattern dynamics, etc.</li> <li>• Hungary makes available all public data. This allowed Janssen Hungary to commence public sector data analytics back in 2008.</li> </ul>
United States	<ul style="list-style-type: none"> <li>• US Department of Defence and Health ResearchTx engaged in a study examining bleeding outcomes for Atrial Fibrillation patients on a Rivaroxaban treatment.</li> <li>• About 70 research engagements in support of real world evidence generation.</li> </ul>
Canada	<ul style="list-style-type: none"> <li>• The Johnson &amp; Johnson Health Innovation Partnership (JAHIP) is a collaboration between the government of Alberta, the University Hospital Foundation and Janssen, which focuses resources on the development and application of real world data and evidence in an Albertan context.</li> <li>• Through effective use of meaningful data generated in traditional health care settings, analysis can inform system decision-making to improve patient outcomes and contribute to health care sustainability.</li> </ul>
United Kingdom	<ul style="list-style-type: none"> <li>• Janssen UK is undertaking a research project using the CPRD database, to help better understand health outcomes in a primary care setting.</li> </ul>
Australia	<ul style="list-style-type: none"> <li>• Johnson &amp; Johnson Medical Devices in Australia has just finalised an agreement with the Integrated Specialist Healthcare Education &amp; Research Foundation (ISHCERF) to measure the impact of innovative health care solutions in multiple disease areas. This is a significant collaboration which includes partnerships with NSW Health, South Eastern Sydney Local Health District, Macquarie University, Laverly Pathology, Ramsay Health and the Surgical Infection Research Group.</li> </ul>

<sup>8</sup> Productivity Commission, 2012-13 Annual Report, p. 12.

## 5. How could governments use their own data collections more efficiently and effectively?

The government needs to take action on anonymising and linking data. In this process there should be consideration into the following factors:

1. Linkage at all levels of health related data.
2. Consultation and partnerships formed with manufacturer, payer, academic and government stakeholders.
3. Encouragement and support for collaboration on data linkage projects amongst the aforementioned stakeholders.
4. Establish a national streamlined approach to requesting data (which includes ethics approval).
5. Look to other countries for tried and tested best practices in data linkage and the utilisation of government data.
6. The government should encourage and support the use of its data in the scientific community – Making it easier for researchers in Australian institutions to utilise data, generate analysis and achieve journal publication using public data at its core.