# SHARON LEADBITTER

### Health policy and market access specialist

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## CAREER

## Consulting

### TACS Healthcare (a division of TACS Australia)

#### 09/2017 to present, Sydney

Principal of independent consultancy delivering reimbursement & health policy services to life science and biopharmaceutical clients, including Nexus APAC, Swain Health Economics, CSL Behring, McKinsey & Co, Insight Strategy, and Commercial Eyes.

Involved in market access feasibilities and submissions to PBAC, MSAC and Pharmac, including on cell therapy. Collaborate with a network of professionals who contribute skills to projects as required.

Preparation of briefs, media releases, bios and submissions to Government on thalidomide, euthanasia, VET, health (NSW election), dividend imputation, osteoporosis, MRI, pharma investment, and a stakeholder engagement plan for a cannabinoid producer.

Spent 8 months of 2018 working part-time with Medicines Australia (MA) in Canberra. Activities included:

- Initiated and led a 'Policy Day' with 50 members from standing working groups in attendance.
- Designed and conducted internal & external roundtables on the refresh of National Medicines Policy.
- Coordinated activities for Access to Medicines Working Group PBS Process Streamlined Pathways subgroup; Joint Oversight Committee for Strategic Agreement & Regulatory Affairs Working Group. This required ongoing liaison with all levels of member companies as well as the Department of Health.
- Managed industry consultation and preparation of consensus documents for feedback to Government on TGA consultations and proposed new Medicines Shortages and Ministerial Discretion legislation.

## **Research-based Pharmaceutical Industry**

Extensive experience with all facets of market access (feasibility, gap analysis & strategy development; planning and preparation of value dossiers; pricing & life cycle management; pre-submission, PASC, PBAC hearings, post-rejection, price negotiation meetings with Government).

#### AstraZeneca

#### 2011 to 2017, Sydney

#### Senior Health Economist, Oncology (4/2014 to 9/2017) Contractor to Market Access (8/2011 to 04/2014)

- Australian market access lead for Tagrisso® (osimertinib), AZ's highest priority product. Worked with Global team
  and local consultant & statistician to develop strategy. Additional payer analyses on individual patient data
  identified clinically meaningful endpoints and a subgroup with improved OS.
  The locally developed economic model based on single arm data matched later Phase III RCT study results. As it
- varied less than the global model in sensitivity testing, it was adopted by HTA markets globally.
  Received one of four US\$50K Global Payer Excellence Grants for my proposed real-world evidence data-linkage
- Received one of four US\$50K Global Payer Excellence Grants for my proposed real-world evidence data-linkage project.
- Accomplished simultaneous reimbursement listing of the EGFR mutation test on MBS and Iressa® (gefitinib) on PBS during the pilot phase of Government HTA co-dependent process. This included a pricing strategy that successfully blocked a competitor entry to the market for over 5 years.

This project was developed into a Best Practice Case Study by the AZ Global Evidence Network for use in training. Publicly acknowledged by Managing Director & Global Human Resources Head as exemplifying Sheryl Sandberg's 'Lean In' principle for my proactive and collaborative approach to this project.

#### **Roche Products**

#### 2010 to 2011, Sydney

Health Economics Manager (1/2010 to 11/2010). This was a maternity leave cover during which I was responsible for preparation of a PBAC submission on Hepatitis C and two feasibility assessments in oncology.

Medical Department (12/2010 to 8/2011). Completed a variety of medical writing, pharmacovigilance, and clinical research projects.

#### Janssen (Johnson & Johnson)

#### Product Development Manager (6/2007 to 11/2009)

Health Economics & Pricing Project Manager (2000 to 6/2007, including 2 maternity leaves)

- Recognised by Global Team Lead, Invokana<sup>®</sup> (canagliflozin) for my proactive approach in bringing Australian and New Zealand opinion leaders together to input into the Phase III clinical development strategy following Phase II results.
- Collaborated with other Health Technology Markets & Global HE colleagues to influence Janssen to conduct an international head-to-head study with Stelara® (ustekinumab) before regulatory approval in any country. The data generated was pivotal to a successful PBAC submission.
- Received J&J Global Standards of Leadership Award for work completed during a 3-month secondment to the devices arm of Johnson & Johnshon. The McKinsey led team assessed the commercial viability of establishing a Diabetes Business Unit in Australia.
- Successfully negotiated changeover period on PBS for a new formulation, ensuring clinicians and pharmacists were informed, that patients were safeguarded, and saved \$2 million in written-off stock.
- Collaborated with Marketing Director and Business Analyst to develop a strategy to increase Pariet<sup>®</sup> (rabeprazole) revenue via positioning on Hospital Tenders. This led to Janssen being awarded an exclusive tender in NSW Hospitals contributing over \$500,000 additional product sales in the first 6 months.
- Acknowledged with a J&J Global Standards of Leadership Award for successful project management of a second major PBAC re-submission of Durogesic<sup>®</sup> (fentanyl) patches. Exceeded best-case scenario in time to listing and minimised price erosion by 30%.
- Prepared PBPA pricing proposals, WAMTC calculations and company price and tender documents.

## EARLY CAREER

#### **Clinical Research**

#### Janssen, Quintiles, Sydney TACS Australia, PR China

Roles with increasing levels of responsibility culminating with extensive on-ground experience in China where I managed Covance's first office in Beijing; worked in a Phase I unit & conducted study site audits.

#### **Hospital Pharmacy**

#### Australian and UK public hospitals

Clinical settings included 2-years as Regional Pharmacist for the Pilbara in WA servicing a majority Aboriginal population.

## REFEREES

#### Available upon request

## LANGUAGE

Mandarin - Intermediate level

## QUALIFICATIONS

Master Public Policy Australian National University Expected 2020

Master Public Health University of NSW

Ass. Diploma, International Trade & Mandarin Royal Melbourne Institute of Technology

Graduate Diploma, Clinical Pharmacy Curtin University of Technology

Bachelor Pharmacy University of Sydney