

New products have always been the building blocks of the Australian life sciences sector. But, with a tectonic shift in health care delivery underway, will new products alone be enough to facilitate a sustainable business? EY's former Global Life Sciences Leader and current Research and Insights Leader, Glen Giovannetti, met with industry representatives in Sydney to discuss the role innovation in the sector can play in a changing world. This paper summarises participants' views on how megatrends are impacting product development; why innovative thinking must expand beyond R&D into business strategy; and what the Australian life sciences sector can learn from other countries.

Globally, populations are aging and non-communicable diseases proliferating. At the same time, the digital revolution is providing patients with new tools and channels for health care, creating more informed and involved customers than ever before.

Health systems are changing profoundly in response to these trends, and payers are demanding new ways of thinking from the companies that serve them. To succeed in this environment, life science businesses must review every decision through the lens of three powerful influences:

- 1. A dynamic definition of value
- 2. The rise of the participatory patient
- 3. The power of big data

Each of these influences requires a move from the traditional transactional approach to new partnership models.

"To demonstrate value, the life sciences industry sector must move from selling products to partnering around outcomes."

Glen Giovannetti, former Global Life Sciences Leader, EY

# Drivers for change

1. A dynamic definition of value

With demand for health products and services rising faster than funding levels, the current system of unit-based pricing for drugs and health care services is unsustainable. It is out of step with payers' budget objectives and no longer reflects the complexities of modern health care.

To help reduce costs and achieve greater budgetary certainty, public and private payers are examining reimbursement systems and placing downward pricing pressure on suppliers. For both policy makers and providers, the overarching goal is to achieve the highest possible level of care for the greatest number of people, with inevitable implications for niche and nice-to-have therapies.

Manufacturers, governments, private providers, investors, medical professionals and patients all have different definitions of the value of care, and even these vary by geography. However, there is a common theme: the option must lower costs and improve patient outcomes. If there is no real world evidence a product can do this within an acceptable timeframe, it is unlikely to attract much support. Increasingly, payers will demand rebates or other forms of risk sharing if promised outcomes are not delivered and the perceived value is diminished.



2. The rise of the participatory patient

With 24/7 access to information, consumers are starting to disrupt traditional health care delivery models. They are evolving from being passive recipients and becoming empowered participants who expect to be partners in health care decision making, including choices about when, where and how they will be treated. This rebalancing of power means patients and consumers will become an increasingly important influence on payers' purchasing decisions.

Furthermore, formerly voiceless patients are realising they can collectively impact health policy. In the United States for example, patient advocacy groups are vocal, highly-networked and have the ear of legislators. Some larger groups bypass hurdles to drug distribution and research by providing direct funding, (e.g. the US Cystic Fibrosis Association) and are strongly represented at regulatory enquiries. Although currently in its infancy in Australia, this trend is likely to increase.

#### 3. The power of big data

The global explosion of cheap digital devices, applications and networks is already changing how individuals manage their personal health. With the advent of social media 2.0 and the Internet of Things (IoT), a generation of digital natives will be empowered to redefine how health care is organised and delivered at a community level.

The new interactive digital landscape will generate huge amounts of quantitative data and qualitative insights. Both will be invaluable for businesses' strategy and planning as they move towards an outcomes-driven world. Entrepreneurs in some countries – including the US and Europe - are already using data to disrupt their local markets.

While privacy issues currently hinder data collection in some jurisdictions, future consumers will be digitally-savvy and open to sharing personal data, especially if they understand how it will benefit them. They may even offer additional information in exchange for treatment.

## The need for a more hands-on government

Despite the Australian Government's innovation agenda, our life sciences industry is being left behind. The regulatory process for drug approvals is painfully slow and government investment in development limited. However, other governments in the region that face similar demographic and social challenges are actively supporting the sector.

Globally, there are many examples of governments investing in innovation, removing trade restrictions, streamlining the approvals process and entering public-private partnerships (PPPs) to support the growth and sustainability of their local life sciences sector. For example, Japan's Prime Minister is driving a reform agenda to improve access to locally-manufactured drugs. With Asian governments supporting the local production of cheaper, 'good enough' products that target both domestic and regional markets, Australian life sciences companies face increased competition at home and overseas. So it is more important than ever that they pursue data-driven innovation on every front.

5 tips on how to succeed:

### 1. R&D

Whether enhancing a current product or researching a potentially disruptive idea, the key question to ask is: "What difference will this make to patients and health care providers?" The more relevant data you can access, the more confidently you can answer this question. Only innovations that can make a demonstrable difference should be prioritised for development, as these will have the most compelling value proposition for stakeholders.

## 2. Commercialisation

The move towards value-based healthcare means the evaluation process that health care providers and investors use for new products and services will get tougher. Suppliers should expect to provide hard evidence to back up answers to a myriad of questions. How will the product improve patient care standards? Which patient segments will most benefit? What are the upfront and total costs? How much will payers save and over what timeframe? Is there evidence of real world outcomes? To support a more complicated assessment process, third party value evaluation tools such as the Drug Abacus from Memorial Sloan Kettering Hospital and the American Society of Clinical Oncology Value Framework are starting to emerge in the United States and similar tools are likely to follow in Australia.

#### 3. Financing

Australian investors have become more risk averse. Small life sciences companies, especially start-ups, can struggle to attract investment due to their inherent risk and long lead times. To support innovation, be prepared to explore alternative fund raising approaches such as crowd funding and seek out opportunities to partner with offshore investors, who are generally prepared to take a longer term view.

### 4. Data

Life sciences companies need to be savvy in their approach to data analytics – accessing existing data and considering opportunities to tap into new data sources from governments, private payers and health providers. This investment will play an essential role in making the case for improved outcomes and enable investors to conduct an evidence-based risk/return analysis, opening doors to greater funding opportunities.

5. Business structure

As access to data becomes the currency of success, the industry is likely to move away from the transactional business model - which traditionally eschews information sharing – towards partnership-based models that support transformation, such as joint ventures, part-ownerships, PPPs and consortia. As well as intra-industry alliances, seeking out strategic partnerships with players in telecommunications, technology and retail can assist with the collection, aggregation and analysis of big data. This may take the form of incubating start-ups that are developing an innovative application, or a data service. With cloud technology growing apace and analytical tools becoming more sophisticated, it will become easier to share information with partners and turn aggregated data into actionable insights. Organisations should, however, be prepared to deal with potential challenges partnerships may entail, including data security and privacy, and devise a reimbursement model that satisfies all parties.



# Glen Giovannetti

Glen Giovannetti is EY's former Global Life Sciences Leader and current Research and Insights Leader. He has over 30 years of experience with EY, the majority serving clients in the biotechnology and medical device industries. Glen has extensive experience in strategic transactions including equity and debt offerings, technology licensing and R&D collaborations, joint ventures and acquisitions.

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