

# Interview with Richard Davies, Managing Director, Amgen Australia

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## What impact have the PBS reforms had on Amgen in Australia?

From a company perspective, biotechnology companies exist in a competitive space. They have predominantly niche medicines with significant competitive advantages and tend to be on their own in a certain clinical space and treatment paradigm. Amgen sells very few medicines via retail pharmacy, so all reimbursement is through the government, and mostly prescribed through hospitals. The challenge for all companies is to demonstrate the value of medicines to the government. It's particularly interesting for biologics, as these treatments are mainly for niche diseases that clinically may not always be that well understood. However, in some cases whilst the PBAC and PBS decisions become complex decisions, they may not have huge budgetary impact for the country. When developing biologics, the question is always one of efficacy. One can always mimic the proteins in the body and when the clinical bodies are tried in the body, the efficacy varies, and why is unclear. But once a protein works, going through phase 2 and 3 and building up side effect profile is easier, because biologics tend to have very low side effects, so once the efficacy gain is understood there are generally few issues in that regard. Clinical trial sizes tend to be small compared to typical small molecule retail-oriented medicines, so Amgen's drugs tend to come to market fast. Most of the discussion with the PBS tends to be around the best way to work with the system to ensure we have time to develop the data that will really help to make a true cost-effectiveness decision around our medicines, while at the same time not denying these medicines to Australians where there is an extremely high clinical need. Amgen's goal is to develop medicines for grievous illness. We're not interested in me-toos or being the fourth or fifth product to market.

Our interest is in developing clinical advantage; otherwise Amgen doesn't develop a medicine. This puts our company very much in the forefront of these discussions of how reimbursement is done. It's a very interesting area and both the PBS and Amgen are learning as we go. The PBS reforms represent a saving to the government, clearly, but beside that the effort is to free up spend for medicine to be invested in the health of the nation by reimbursing innovative medicine. When it comes to medicines characterized as biologics, we're at the tip of a very big iceberg. In the past, there was a tendency to think of the drugs as one-offs, but the time has come to think about how to legislate effectively, to allow access and at the same time help medicines work their way through the PBS system. We've been hearing from a number of sources that the future of Australia's manufacturing lies in innovative areas, in addition to a strong R&D and clinical trials base.

**With biologics representing an important part of that, how would you rate the receptiveness of the Australian environment in these terms?**

Having worked in 20 markets around the world, I can personally say that being in Australia in a biotechnology company is an immensely rewarding experience, and one thing that drives that is the openness and the willingness of government and the bureaucracy that supports it to engage in meaningful conversations. You can take those as relatively trite words, but I completely believe it. Whilst we don't always agree, I take a huge amount of value as an executive from the discussions with the government and the bureaucracy because as a group they are trying to manage the healthcare of a whole nation through taxation. That's not a task to be taken lightly or easily by anyone. Recent discussions with regulators have led to the registration for N'plate, which is Amgen's new medicine to treat Idiopathic Thrombocytopenic Purpura (ITP). Amgen was asked by the CJ to work with them on a project to significantly reduce time to registration through joint review, and we're absolutely delighted with the partnership through the TGA, which resulted in a first in the world registration. Such initiatives allow Amgen to get medicines to patients faster, and at the same time establish safety and efficacy in the mind of the government. For an executive and company, Australia represents a very open environment. With respect to the PISG, the task is enormous. The industry has many assets and multiple players, going beyond just generics versus innovators; we need to start to look at the industry drivers. And if the government's question is in investment, then there are many areas to investigate: plant materials, manufacturing processes, intellectual capital of the workforce, researchers and creating innovation. It's important to create that innovation and ask how much you can hold onto before the need arises to bring in big Pharma or a big biotech company because at a point, it's an issue of funding. It could be a case of \$5 million for phase 1, \$50 million for phase 2, and \$500 million for phase 3.

**The PISG needs to see past the question, because many companies are from larger corporate organizations and we need to step back and ask, what drives the larger corporations to invest in a given country?**

Looking at Australia's history, as a country with 20 million people, research and development has punched above its weight statistically. Amgen reflects that, with 10% of clinical patients in total taken from Australia. And that's the case because Australian researchers have the skills to explore new chemical entities and biologics of the future. Amgen partners to help them invest in and understand new disease areas. Australia has key positions in world thought leaders. In osteoporosis for instance, there's a disproportionate amount. There's an imbalance between the country's market potential and the potential to partner in other parts of the business. The required investment for a new biotech plant for Amgen is \$2-3 billion and these decisions come up rarely. As a strategy, different subsectors have different drivers, whether large or small bio, of which the latter needs to be nurtured, whether through hubs in Victoria or Queensland. BioInvest Australia has been creating an incredible fertile partnership ground and in the last few years Amgen has signed over 10 deals, most recently with La Trobe and CRC Biomarket Translation.

**You mention the large drivers globally, but what are the drivers for Amgen in the local market?**

Taking out North America, Australia falls in the top six of Amgen's markets worldwide. This positions us as a critical market of similar importance to Germany, France, or Italy, although Amgen is present in far fewer companies than a typical Big Pharma. Amgen does first in human studies in Australia and it's rare for American firms to do that outside of America. This really demonstrates a high level of trust between scientists and physicians. Amgen sees this as a huge plus for the business and it's a significant part of the local research arm. In Australia, Amgen employs as many people in research as commercial activities, which are run with 20 highly skilled, highly focused and well trained representatives. Amgen is very much a leader in launching therapeutics first. Amgen seems to be doing well in Australia – excelling in clinical trials, R&D, and new product introductions.

**Clearly in addition to the country itself, Amgen is also punching above its weight. To what do you attribute this success?**

Amgen is a company that when it enters into a country, the R&D effort is equally important as the commercial effort. This is for a number of reasons and the most obvious is the helpfulness for approval in having clinical trials in the country where the drug is being approved, along with patient accessibility particularly in chronic diseases. Amgen spends twice as much on R&D than commercialization, which is a unique ratio in the industry. In Australia, Amgen has been able to for many years establish a business model for success. We have a strong R&D and commercial marriage, layered overtop by the ability to partner locally with Australian companies. This makes it a very exciting business in which to be involved, and only adds to an already exciting portfolio of medicines for clinicians, whether in research or use. One of the three stakeholders you mention is employees.

**With previous experience in the US, UK, Poland, Vienna, and the Middle East, how would you characterize your management style?**

I would characterize my style as collegiate, tough, quick and decisive. I'm a very team-based person. Doing business now is so much more incredibly complex than even five years ago, so it's important to try to manage multiple functions and business drivers all the time. It's important to drive a series of behaviours whereby you can bring a team of people together who represent different things. They may have different motivations, but they must absolutely be aligned around a goal, and at Amgen that goal is to serve patients. As a leader I work hard to understand what drives and challenges people, where to compromise and when to make decisions. But this must be done quickly; there's no time to stand around. Amgen is a very nimble company and it's important to get aligned fast and flawlessly execute with a team of very smart and very bright individuals. Any executive must have a style that accommodate that, and the days of telling your staff what to do are certainly passed, if they ever existed.

**In talking about aligning people around a common goal, looking toward your vision in the next five or 10 years, where do you want to take Amgen?**

**The great thing about working for Amgen is that at times when we reach an impasse, the thing that breaks the deadlock always comes down to answering the question: "what will best serve the patient?"**

"Asking how the company will serve the patient has always been the touchstone and guiding light, a driving force as we work through decisions that are rarely black and white.

**The goal is to reach all those patients who will benefit from the medicines. How do you plan to achieve this goal?**

We're doing the set-up now. In 2006, Amgen kicked off a project called "Drive to 2010", which perhaps should have been called Drive to 2015. The direction and build were correct, but we can back into a change in timeline. The plan called for capability in local development and access, to improve communication with government and bureaucracy, and understand submissions to PBS and HTA. Amgen has done some fine-tuning to the strategy, but realizes that the right road was set, even if the decisions made back then felt hugely risky. Amgen has always been a high gain company, and is in a position where revenue will soon be doubling today's figure. However, what's important is getting medicines to patients where they're going to benefit, and if the company does that its size or ranking is irrelevant.

**What is your final message about Amgen serving the patient in Australia?**

As a company, Amgen strives to bring its medicines to the market with appropriate data at the appropriate time and history will judge how well this is achieved. Amgen is excited by what we're

doing, and it's not easy, but right now we're pleased with where we are.

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