

Interview with Andrew Carter, Managing Director, Commercial Eyes

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Challenges facing pharmaceutical companies in Australia today?



There are four major challenges within the Australian pharmaceutical industry at the moment. The increasing complexity of getting a medicine registered; getting a product reimbursed via the Pharmaceutical Benefits Scheme (PBS); dealing with the challenges of PBS reforms; and, the difficulties raised by a tight labour market within the industry itself. These are some of the significant issues we discuss with our clients on a daily basis. Firstly, from a regulatory perspective, a company needs to know what the requirements are, whether these requirements are unique to the Australian regulatory environment and how they can navigate the regulatory process. For example, a research based pharmaceutical company, may need to invest in extensive liaison with a corporate or regional office regarding the Australian specific requirements, whereas if the company is a generic supplier, they may need to determine which bioequivalence study is likely to be accepted here. Secondly, PBS reimbursement raises many challenges. For new companies coming into Australia, they need to familiarise themselves with a new and unfamiliar system and it isn't much easier for established companies. Given that many companies operating in Australia are subsidiaries of multinationals, a Managing Director may only be here for a relatively short time – sometimes only three to four years. The PBS is not an easy system to understand and senior executives spend a lot of their time trying to come to terms with it and communicating its inherent issues to their head office. Many come to Australia knowing that the prices they are likely to achieve in Australia will be lower than in other countries. Although equipped with the expectation of pricing challenges, they are often not prepared for the sophistication of the process. From a health economics perspective, Australia is the world leader and prides itself on being sophisticated and rigorous. Pharmaceutical companies need to understand the reimbursement process, how to resource adequately to manage the submission process and finally, what is a realistic measure of success. In order to put this in some context, in a regulatory sense approximately 93% of applications are successful and of those that are rejected, most sponsors were aware of the specific problems that led to the rejection. Conversely, within the PBS environment, despite the significant costs and complexity, there is no guarantee of a PBS listing. The government wants some certainty that when a product is listed on the PBS it is not going to cost more than what was predicted. In the same way, company executives want similar assurances of a successful reimbursement outcome. In short, they want the confidence they have in the regulatory process to be replicated within the PBS process. Thirdly, the PBS reforms have further complicated the reimbursement process. The government has put in place a range of mechanisms specifically targeted at genericised products that reduce the price of a product. However these reforms have had a flow on effect beyond generics, impacting products still under patent. Pharmaceutical companies are faced with the challenge of delivering a return on investment

and as such traditional sales and marketing models are being challenged. Finally, we are operating in a very tight labour market with a reasonably high turnover within the industry. Optimising resources is a significant issue which can be complicated by the high costs associated with the regulatory and reimbursement processes. Good technical people are hard to find and as a consequence high demand encourages equally high movement between companies. The constant changes in staff, driven by high demand, make it very challenging to retain knowledge and expertise within a company. This is why companies like Commercial Eyes are such a valuable ally and asset. Pharmaceutical companies need to develop an appreciation for the amount of work and the investment required, the feasibility of the opportunities the Australian market presents and what resources they are going to have to invest in to make it a viable option. In addition, following the regulatory and reimbursement hurdles, they need to work out what sales and marketing model is going to give them the best return on their investment in Australia.

Commercial Eyes offers expertise in each of these areas and therefore plays a significant role in assisting pharmaceutical companies to navigate the uncertainty of the commercialisation pathway and be successful in their efforts. What makes Commercial Eyes the partner of choice?

We consider ourselves to be the experts of the commercialisation process because that is what we do. At Commercial Eyes, we start with the end (i.e. the market) in mind and work backwards. We don't do drug discovery or clinical trials which means that unlike service providers that operate in a similar space, our entire business is commercialisation. We assist in the development of commercialisation strategy, provide market and product feasibility analysis, we prepare regulatory and PBS submissions, medical information and pharmacovigilance, assist with product launches, marketing and lifecycle management, right through to dealing with the challenges of post-patent expiry competition. Commercial Eyes also works across the healthcare sector. We don't just prepare reimbursement submissions or regulatory submissions (just some of our services), or provide assistance to just one type of company or within one segment of the market. Commercial Eyes is very client-oriented and has a comprehensive understanding of our client's operating environment. Our reason for being is to help our clients realise their full potential. Commercial Eyes recruits highly regarded, experienced and knowledgeable industry professionals. We recruit people that have worked in the pharmaceutical, biopharma and medical device sectors for a minimum of 10-15 years. Commercial Eyes employees have to be able to demonstrate a breadth of knowledge that allows our clients to have complete confidence in the commercialisation process and in our ability to facilitate the best possible outcomes. The fact that our staff has had vast experience across the industry is clearly a bonus. And finally, I believe we are the partner of choice because of the breadth of experience that we offer our clients. Commercial Eyes has worked for over 200 companies from all over the world. The vast majority of our staff has science, marketing and business postgraduate qualifications and we have a very significant technical know-how that is the basis, but not the end point, of our work. In situations where we don't have in-house expertise, Commercial Eyes identifies consultancies to ensure full service delivery. For example, Commercial Eyes has an alliance with the statistics group at the University of Melbourne.

Throughout our history, Commercial Eyes has been able to position itself as a true commercialisation strategist to our partners. How does Commercial Eyes remain an attractive place to work in the tight labour market you mention?

To start with, we compete with other prospective employers by providing our employees with the basic necessities such as competitive remuneration, a good working environment and benefits amongst other things. If you can't do this first part, offering a great health plan is not going to do anything for the company. So, our first step is ensuring that we are at least competitive with what the market is offering. The second thing that we offer is a very flexible work environment, allowing

employees to work from home or at times that suits their family situation and lifestyle. That has been very attractive to our staff. Many have a family and appreciate the opportunity to do things their own way. If it is Tuesday and they want to work from home, they can do so. The third aspect is the diversity of the work itself. A member of our team may work on reimbursement for a medical device one week and on an oncology submission to the PBS the next. Our staff has a diverse range of projects to work on that are both interesting and challenging.

For a relatively new and small company, Commercial Eyes is surprisingly dedicated to Corporate Social Responsibility? Can you talk about the importance of this to the firm?

Corporate social responsibility is a central aspect of the business for me. I believe very strongly that working in a health care consultancy has enabled us to know our way around health care issues and that we have a responsibility to use that knowledge for the benefit of others. Commercial Eyes made a commitment early in its existence to financially support the community in which we work and therefore contributes a minimum 1% of our revenue to community work. We chose revenue, rather than profits, because it is clear cut and transparent. We have also established a community council with seven members of the organisation who, on behalf of Commercial Eyes, identify areas of need that could benefit from our support. Commercial Eyes also provides pro bono work for certain organisations that are trying to understand government processes. We believe that corporate responsibility is absolutely essential but it has also made us an attractive employer and assisted with employee retention.

What is your strategic vision for the company's future?

We do quite a lot of work for companies that are based in South East Asia and also those wanting to expand into the region. As such our plan is to establish ourselves in Singapore next year as our first sojourn into this rapidly developing market. There are a number of reasons we have been able to grow our business in Australia and we plan to replicate this model and growth in Asia. In Australia, we have identified service areas that we believe are essential to helping companies move forward. We've been able to offer a range of capabilities that support emerging companies that don't have the full range of resources in house whilst providing larger established companies with the opportunity to outsource some of their functions to us once they have considered the efficiency and economics of doing so. The growth of our business is important. Given the competitive environment here in Australia, geographical expansion into South East Asia allows us to take our business further and provide our clients greater support across the region. We have been able to grow rapidly in Australia and have a reputation for excellence in both quality business outcomes and working relationships. The Australian market trusts us, however with bigger projects often a regional office will be involved in a decision. It makes sense to try to ensure that those regional offices also have the opportunity to know and trust us and as a result support the decision to work with Commercial Eyes into the future.

Given the rather specific nature of the business, what will be Commercial Eyes' approach entering to new markets?

Many of our existing clients believe that we will be welcomed into the Asian market because of the assistance we've already been able to provide to them here locally. We know success rests on engaging locally and have already started to identify highly experienced professionals in Asia that are interested in joining the Commercial Eyes team. We intend to provide an infrastructure that leverages our existing competencies - proven here in Australia - into other markets. We are very grateful of technologies such as the Internet, which allows us to transport and take advantage our knowledge with a modest amount of modification to other environments.

What is your final message to the readers of Pharmaceutical Executive?

I think it's important for senior pharmaceutical executives to acknowledge the unique complexities of the Australian (and broader Asian) pharmaceutical market and to address those complexities sooner rather than later. Forewarned is forearmed. Commercial Eyes is in a position to assist with the navigation of almost every aspect of commercialisation and given the considerable interest that has developed in recent years in the Australia industry and more broadly in Asia Pacific, we have been able to help more and more clients to streamline and simplify the process. It's so important to be on top of the issues and to get it right when it comes to commercialisation strategy, regulatory affairs, reimbursement, lifecycle management, marketing, pharmacovigilance and government liaison. Commercial Eyes offers assistance in all of these areas but whether an executive chooses to utilise our expertise or not, they need to understand and perform in all of these areas to hopefully achieve greater success and realise their product's full potential.

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