Interview with Joyce Lloyd and Munro Neville, Managing Director, Director, Medical & Operations, Pretium Australia

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Tags: Pretium Australia

Would you please introduce Pretium's specific service offerings, and the focus within these?

Pretium offers a comprehensive range of integrated services across our 4 lines of business – Market Intelligence, Health Economics, Late Phase Research and Disease Management. The distinction between the various stages of a product's life cycle and the services required to support them is not always clear cut. Research activities occurring during the early stages of product development may flow on to effect arguments for marketing approval and submission for reimbursement down the track. It is, therefore, important for us to understand the stages of the Australian pharmaceutical market life cycle to facilitate an effective and integrated approach to supporting products locally through our 4 service lines. Market Intelligence services are often initiated long before a product is launched. Market access strategy is very important for any new product. Especially in a largely government funded health system like Australia, a company will need to have a funding strategy that takes into account public and private systems, as well as have assessed opportunities for listing and reimbursement strategies. Market analyses are conducted to understand the competitive landscape and provide an understanding of the product's value and potential positioning. Pretium's Market Intelligence arm undertakes desktop research, conducts interviews and surveys with health care providers to elicit expert opinion, and collaborates with industry bodies and government associations as required to produce recommendations and reports

that assist in shaping the strategic direction of products in the Australian environment. Health Economics work at Pretium is primarily focused on development of submissions to the Pharmaceutical Benefits Advisory Committee (PBAC) and obtaining listing on the Pharmaceutical Benefits Schedule (PBS). This usually takes the form of large complex submissions in which we need to prove that a product is either cost-effective or will provide equal clinical benefits as existing therapies at no extra cost. We also need to assess the impact on the Australian budget for a new product, and rationalize reimbursement opportunities. This means identifying the place in therapy, producing clinical and cost-effectiveness arguments for listing, and presenting cost-to-government budgets. In Australia, the process is similar to the UK NICE system, although more onerous. It is a huge hurdle, and one of the unique things about the Australian system. As such, Australia can be considered a pioneer in using health economics to manage access to pharmaceuticals. Getting the reimbursement strategy right is a key focus for much of our HE work. Late Phase Research at Pretium involves clinical research in the later phases of a product's life cycle, often in primary care where real world data are obtainable. There is a real gap, globally, in data collected post-regulatory approval phase and in real practice settings. Considering the growing need for these data, potential provisional listings, demand for both clinical and process outcomes data, and the increased focus on pharmacovigilance activities, we see this as a huge area of growth for Pretium. Early phase studies typically have not been designed to support positioning, pricing and reimbursement strategies, and this again is where Pretium comes in. Studies are also undertaken to collect local data necessary for development of credible reimbursement arguments. Pretium's ability to conduct research in primary care is unrivalled in Australia. Pretium has trained GPs how to do clinical research and essentially developed GP investigators, which is a real challenge, because they are so busy. Our GP network relationships provide reach across all of Australia and facilitate speedy recruitment of large pools of experienced GP investigators. We have just finished the largest double-blinded, randomized controlled trial in general practice in Australia, with over 200 GP investigators and our mobile study nurse coordinators. As a provider of Royal Australia College of GP accredited QA&CPD education, we also develop research education programs to support GP research, further reinforcing the principles of ICH GCP and critical study procedures. Disease Management is a well-defined industry in the US market. In Australia, the private health funds understand what disease management is, and understand there is good reason to invest in it. When Pretium defines disease management in the Australian pharmaceutical industry context, we mean an array of tools, support programs, guidelines, our disease management practice nurses and health care professionals delivering systems of care to which pharmaceuticals are pivotal. Disease management programs enhance value, drive appropriate and quality use of medicines, improve performance and drive differentiation, while integrating into the current delivery systems and funding structures. Our nurse teams provide coverage across the country and work with GPs and specialists to provide improvements in the quality of care and also help fill gaps in the current health delivery systems. Disease management programs are designed to maximize health and

process outcomes, through the integration of behavioral and pharmaceutical interventions. That, in a nutshell, is what disease management means to Pretium.

How does the particular Australian environment provide business challenges or opportunities for a company like Pretium?

Undoubtedly, successfully listing drugs on the PBS in Australia is becoming more difficult. The burden of proof and the height of the hurdles are becoming more challenging. The amount of data collection and work involved in preparing and presenting a convincing case to government is significantly more than it was even 3 years ago, and more so than in other countries, requiring a lot of customization of global approaches to funding. Most companies use what are called “global value dossiers”, as part of an overall approach to seeking funding, but these are often of limited use in Australia. Much customization is necessary to satisfy the requirements of the PBAC, in addition to work by the local affiliates in educating the global headquarters about why they must deviate from accepted pathways. This results in quite a complicated and involved process that can often be frustrating for the local affiliates, but provides an interesting opportunity for Pretium. For example, many global health economics models are not sufficiently robust to pass the highly in-depth and complicated evaluation process that the PBAC employs in its assessment of product value.

You speak to the need of multinationals requiring Pretium’s services, yet aren’t these large companies the ones with the capacity to perform these tasks internally, rather than outsource?

Most companies still rely on consultants to provide specialized services, such as complex health economic models and late phase studies designed to collect real world data. Companies may have sufficient resources, but there are very specific technical skills required to do some of this work and a very limited and finite pool of such expertise in Australia. Pretium becomes involved in the development of global HE models that have a greater degree of flexibility and robustness around assumptions in these models so they can satisfy the local market. What needs to be shown in the UK, Canada, or the US is different, but the structure can have commonalities. In the end, the models must demonstrate a high degree of proof that assumptions, inputs and probabilities within the models are likely to be reflected in the actual Australian market post-listing. Large companies have global teams that develop global models to meet different market requirements, but because the methodology required is unique and more onerous, a certain local knowledge is required for customization. The goal of some PBAC members of establishing Australia as the world’s global model for drug funding has been somewhat unrealistic to date, as the country accounts for only 1-2% of the world market. There has been little incentive for pharmaceutical companies to collect the data required for funding submissions in Australia. However, the Department of Health and Ageing (DoHA) share a vision and support this goal, which includes visiting countries in the Asia Pacific

region, as well as the UK, parts of Europe and Canada to standardize approaches to funding decisions. Presenting submissions to the PBAC is complicated and may have significant data requirements. It is hard to imagine a research initiative that can satisfy all the criteria. The expectation for data can be unrealistic and some of the data could require years to gather. Access to data is not always an easy hurdle to overcome and can present quite a challenge.

In Australia, areas of uncertainty that data gaps present can be used as a negotiating tool to reduce price of pharmaceuticals. Is this a reasonable expectation?

Over time, I think it will achieve more traction, and people will listen incrementally, especially in other markets continuing to struggle with issues in public funding and health. The demands of the PBAC in Australia alone are unlikely to change major pharmaceutical companies' research and development, not with the weight of 1-2% of the market, but it is unclear as to whether there is a tipping point, as more countries employ health economic approaches to ration access, beyond which the industry as a whole changes its approach to research and development.

How is Pretium different from other consulting companies serving the pharmaceutical industry?

Companies do make the decision to work with larger consultancies, but there are advantages that smaller, local firms can provide that larger businesses simple cannot. Pretium has unparalleled local knowledge, experience, and technical skills. Larger competitors often do not have the technical skills and the detailed local experience to get the job done. Interestingly, Pretium ends up having to fix a lot of work from big global players. With regard to Pretium's late phase clinical research compared to the big global players, we are nimble, quick, responsive, and focused. We can be flexible and innovative, unbound by global policies and layers of bureaucracy. A lot of the big global players simply can not do that. An established, global company will have a global template, and if you have something that doesn't fit within that, the solution won't happen because they don't have the creativity culture or the time to focus on tailoring a solution. 1% of the world market is not going to drive their client management strategy, Pretium on the other hand can is focused 100% on Australia. We can develop large sets of data quickly, and this speed is critical. In the future, we believe there will be a demand for large international data sets post-TGA or FDA approval and that will include the type of data we are collecting in Australia. Another difference with Pretium is our experience in designing and implementing disease management programs within the unique health care delivery infrastructure in Australia. Although the American and other health systems share similar components of the Australian funding model, the public funding system in Australia is quite different and presents challenges. The primary care funding model is transaction oriented, providing reimbursement for units of care with some incentives paid for improved care processes. In addition, the Australian health care funding mechanisms (private health funds and government pharmaceutical, medical benefits and hospital benefits) are fragmented. As a result,

the system creates gaps where the continuity of care and coordinated care can represent real challenges. Pretium can use disease management programs to fill these gaps in the system and improve the coordination of care. Typically, our disease management programs involve an appropriate use and quality use of pharmaceuticals approach, specifically integrated with behavioral health interventions and systems of care to help achieve optimum health outcomes. There is just no one else in Australia who has the expertise and knowledge of these models, plus the experience in execution. There is a risk to pharmaceutical companies in hiring their own health care professionals to deliver health care interventions and we have seen a huge trend in outsourcing now. Pretium provides that arm's length opportunity to deliver quality programs while driving the overall objectives of the pharmaceutical company.

Can you talk about the receptiveness of companies using an arm's length organization to come in and provide services that are arguably core to understanding the markets they serve?

There is definitely an increasing demand for responsible marketing approaches in Australia. This is causing a shift from traditional ASP spending to more on creative programs to drive those critical marketing messages. This trend has particularly being seen in the US over the last years, where the numbers of sales representatives are falling dramatically for a number of reasons. For one, reps are often ineffective because doctors are too busy to see them. Now, sales representatives stand in a queue to hand somebody a glossy piece of literature. The environment has changed. Transparency is another issue which is changing the way pharmaceutical companies market their products. Spending money on expensive conferences, fancy hotels, lavish dinners and shiny pens is going away, and the era of responsible marketing is taking over. How quickly companies change will probably be a function of their size and culture. We've already seen a huge downsizing in sales teams and increasing investments in supporting the actual delivery of health care interventions that include the appropriate use pharmaceutical products. It is in this change toward responsible marketing that we see a huge opportunity to deliver quality health care programs to support pharmaceuticals here in Australia.

Do you see an opportunity not only in the larger companies but perhaps in the smaller biotech space for instance, which counts over 400 biotech startups in Australia?

This represents a huge opportunity, especially with our market intelligence services, but also with our research and disease management services. It is interesting to see that the activities of traditional companies in the area of oncology, for example, are the same activities that biotech will undertake as their products become a reality. Many are doing a lot of work in oncology and as cancer is considered a chronic disease, the same patient support and disease management initiatives will be important to the biotechs. What Pretium does for patients who are potentially eligible for specialized high-cost, low-volume products, is similar to the patients with chronic

diseases covering asthma, diabetes, mental health, and obesity. There is definitely a large potential for biotech companies to benefit from adopting the disease management approach to delivering integrated behavioural and pharmaceutical interventions.

In terms of targeting these companies, are you going after them or are they coming after you?

Australia is a small market, there aren't a lot of players, and there's nobody doing what Pretium does. No one offers the comprehensive integrated services that we offer. There are companies to use for outsourced contract teams to deliver some interventions, but none have the operational expertise combined with the expertise to design and deliver programs from beginning to end, right through to data collection and publication. Pretium benefits from a great reputation, which we have earned through a lot of great work. Word of mouth in a small industry where people are constantly moving from company to company can be very powerful. And because of this we get approached by all different types of companies large and small, and this includes biotech and device companies.

Speaking to the people side of things, where does Pretium find the kind of highly-skilled employees with the necessary local experience and knowledge of the local market?

Pretium develops and trains talented people, and spends a lot of time and effort doing so. The company is a great team, has incredibly low turnover, huge loyalty, and a lot of that comes from the satisfaction that is derived from delivering positive outcomes. Our innovative, flexible culture is very appealing to bright, creative and passionate individuals. We say we love what we do, and it is the truth. Some of our best team members were former clients who approached us with an interest in working at Pretium. That is a huge testament to the culture at Pretium and the respect we have cultivated. We have always felt that success breeds success, and the successful individuals that have joined and helped create Pretium also draw other talented people to the organization. It has been a terrific win-win situation in that we have brilliant people, and companies are people after all.

How would you describe working at Pretium?

Pretium provides a fun, intellectually challenging, and collaborative environment that celebrates successes. At Pretium, we keep a completely open mind, thinking beyond the four squares in our logo, which has just been redesigned in late 2007. Each of the 4 squares in the logo represents one of the 4 service areas, and the blurring represents the overlap we often see across the services that no one else provides. For example, a pharmaceutical company will talk to Pretium about doing a disease management program, but then they say, "here's the information and data that I want". At this point we realize that a late phase study approach is required, and will therefore apply the rigor required for that approach. A health education or outsourcing company cannot manage that transition, but Pretium can, as well as many other combinations of models and

approaches. The overlap and the need for that comprehensiveness is so obvious that it works. And our people love working in an environment where there is a solution to every challenge, and the fact that they are part of the solution is even better.

Where do you want to take the company in the next 5 to 10 years?

It is Pretium's aim to succeed in Australia, and to dominate the market in each of our 4 service areas. And we're already close to doing that. Historically, the company hasn't had an aggressive business development approach, with most business coming from word of mouth and repeat clients. This is a testament to the organization, and the way in which we work with pharmaceutical companies early on and through the entire product lifecycle, through reimbursement issues, collecting data, and marketing with a more creative approach through late phase research or disease management programs. Much of Pretium's focus now is on developing a well-defined business development strategy to help grow new business opportunities and help expand our existing business.

What do you expect the biggest organizational changes to occur over this period?

Pretium will have more people with specific technical experience across the pharmaceutical industry, providing each of our services lines with greater depth and capacity. The business environment will change, creating a greater need for ongoing monitoring, which will work well alongside companies that are flexible and responsive to the needs of their environment. What we would like Pretium to gain over this period is mature market dominance and for the company to undertake some work outside of Australia, thereby contributing to the local research industry.

What potential do you see for Pretium expanding outside Australia?

The company already does a small amount of work overseas in Europe, the US and New Zealand, in customizing global models and other HE work, although this is more as a partner to the affiliate. Increasingly, Pretium will look towards key markets in Asia Pacific, the US, and Europe. But we want to take care of Australia first.

What is your final message to Pharmaceutical Executive readers about Pretium and the pharmaceutical industry in Australia?

The message is that, although Australia represents 1-2% of the world market, there are novel approaches possible here, and there is a good reason for other markets to look at what's happening in Australia, and to invest in Australia's research and development industry. Over time, the Department of Health and Ageing and their incremental approach will slowly increase the importance of the Australian way in seeking drug development and access. It may not become the dominant approach, but it will become more and more important, and more markets will evolve in a similar manner. There is a move afoot for greater standardization of health technology assessment

(HTA) organizations and their approaches, and that will slowly gain more traction as well. Timely late phase research in a real world environment will be a critical component of the contribution that Australia can make going forward. On the disease management front, because the system is so fragmented, and we believe will continue to be for some time, there are very interesting solutions to the fragmentation that will provide opportunities for creativity within the framework of behavioral health and pharmaceutical interventions. We are confident that Pretium will be at the forefront of our markets and will be leading the charge in the evolution of the pharmaceutical industry.

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