Interview with Gary Hendler, President & Chief Executive Officer for Eisai Europe Limited, Eisai Europe

30.07.2012

Tags: Eisai Europe

As the head of Eisai's European operations, how would you assess the relevance of the European market for Eisai's global operations when compared to the US or emerging markets?

Gary Hendler (GH): Eisai are currently present in 17 European markets as Eisai and several others via distributors. However it is difficult to compare this region for Eisai with others around the world precisely because of the complex sales structure that we have. Historically, Eisai partnered with other larger and well established pharmaceutical companies such as Pfizer and Janssen to enter the European market but Eisai only books the sales for Aricept, our blockbuster product for Alzheimer's disease, in Germany, France and in the UK. All sales in other European markets where Aricept is marketed are booked by Pfizer either as our licensee or as our co-promotion partner. For this reason it is difficult to measure Eisai Europe's contribution to the global operations in terms of sales. If we booked all the sales for Aricept in Europe, we would be looking at around $700,000 per year at the moment, compared to the US sales last financial year which were approximately US$1.8 billion in a market where sales are exclusively booked by Eisai.

This goes to show that if the company was booking all of its sales in Europe, and we took into account the exchange rate, the footprint of the Eisai European market would be improved significantly compared to that of the US in terms of sales. Pharmaceutical companies are usually ranked and judged in terms of their sales, which makes it difficult for our European operations to be relatively and fairly compared, simply due to our current business model. This is part of the

reason why Eisai is trying to move away from the past sales structure and replace the existing business model with a new business model to structure to run operations even more effectively in the European region. In the last five years Eisai has been moving away from the historical approach by establishing its own businesses outside of the five major European markets. For example, we have established a Nordic operation based out of Sweden that covers the five Scandinavian markets, as well as subsidiaries in Austria and some of the Eastern European countries.

The new European Knowledge Centre facility that we have in Hatfield, Hertfordshire in the UK is symbolic of this new approach in operating in the EU market and brings all components and disciplines together under one business entity. This is also fairly progressive when compared to how other pharmaceutical companies operate. In addition, we have decided to move to a “One Europe, One Team” concept, in which the operations are run as ONE entity. One of the driving reasons for this is the disconnect that previously existed between the European strategy, decided centrally, and the independent decisions of each country and individual subsidiary company in execution of the strategy. The “One Team” approach, launched in April of this year, has shifted the focus from being country-specific to becoming European-specific. Now each country operates as a business unit that reports into a single European Business Unit constructed by therapy area and/or business synergy. Each business unit is led centrally by a European Business Unit Director based here in the UK and reporting directly into me as the Head of the European operations, rather than having each country report into their General Manager. The in-country business unit director will oversee the sales force and marketing for that market allowing for aligned local execution while the leadership is centralized here in the UK.

As a consequence there will be a single profit and loss statement rolled up for the whole of Europe per business unit, which means that accountability lies across Europe even though management and control is here in the UK. In order to standardise our European business practices, we also have had to change and adapt everything in the way we operate to change our business model in Europe, from our business support platforms to our support functions and customer relationship management systems. For example, we have just launched a new European enterprise resource platform across the whole of Europe. This will allow us to monitor the business performance in real-time and on the same financial reporting platform. This kind of structure and connectivity will give Eisai much more flexibility in analyzing our opportunities on a return-on-investment basis and therefore to make better and faster business decisions. Having a single profit and loss statement per European business unit, will allow for making decisions that benefit the region as a whole and not on a per country basis. This is quite cutting-edge and potentially more progressive than traditional business models still deployed by other pharmaceutical companies in Europe.

Given this move to restructure the regional operations, what will be the main growth drivers and the greatest challenges that Eisai will encounter?

Our main growth driver as a research-based pharmaceutical company will always be the launch of new innovative products. Eisai has decided (at least for the mid-term) to remain focussed on the core business of developing innovative prescription pharmaceuticals in house. Another driving factor for growth will be shifting our business model to become more independent. Due to the upcoming loss of marketing exclusivity for Aricept in Europe, a harsh reality that we have had to face is that the company will go through a challenging period with sales shrinking in gross terms. However, because of our move to become more independent and gain direct control over our sales by launching new Eisai products, we believe that we will actually experience a relatively rapid rebound in our sales. Within our European operations footprint, we are also still planning to move into new markets. For this fiscal year alone our priority is to move into three specific markets, despite the challenges that we will face by doing so. The first priority is to establish a presence in Greece and in doing so change, for future products, the nature of the current arrangement that we have with a local distributor business model for our existing products. We recently established a commercial operation in The Netherlands and now plan to enter Belgium and Luxembourg which together will serve as our BeNeLux sub-region. We also plan to prioritise entering Poland, which is a large European market opportunity, and therefore significantly increase our presence in Central and Eastern Europe.

Nick Burgin (NB): As regards the challenges, undoubtedly the most important barriers that we will face are related to the austerity measures that are being adopted by governments across Europe. This includes mandatory price decreases and the move by European payers to recognize less value in innovative medicines. Japanese companies are currently in an investment phase in which they are looking to spread their wings and invest in new markets outside of Japan. As with any investment decisions there are limited resources available to these companies and therefore they will choose the most attractive opportunities for them. Emerging markets such as the BRIC countries are very interesting options for these companies and therefore markets in Europe must compete for these investments by sustaining an appealing environment through investment-friendly policies.

G.H.: Another challenge of operating in Europe is that people tend to think about the region as a cohesive and uniform market, which is quite misleading and oversimplified. Having said that, the major similarity that European countries have in common is a centralized regulatory procedure, which allows for identical labelling of our products in the member states. For a pharmaceutical

company such as Eisai, the reality is that everything else that concerns operating in Europe is entirely different from country to country. This includes different healthcare systems, pricing and reimbursement processes, pharmaceutical codes of practice and obviously language and cultural differences (not to be underrated) in each country, not to mention the fact that there are a total of 38 markets in the region but only 27 that fall within the European Union itself. These means that we could negotiate up to 38 different prices for our products as opposed to having one single official list price, as is the case in major markets like the US, China or Japan. The exciting challenge for us is to bring the differences and similarities of all these countries under one Eisai European business model as opposed to a business model that is the sum of all its parts.

A couple of years ago Eisai built the European Knowledge Center in the UK as a platform where the company's European expertise can be integrated at one single site. What does this initiative represent for Eisai's product pipeline?

G.H.: This was the first step for Eisai's new focus to shift its business model to a more independent, standalone operation. Traditionally, Eisai would manufacture the active ingredient (API) for its products in Japan and then would ship the API to a toll manufacturer in Europe that would then transport the finished product to a third party packaging facility in a process that made the global distribution of our mainly low volume products very complex and expensive. By building a manufacturing center in the UK and locating it on the same site as other teams and departments at the European Knowledge Center, we have been able to coordinate manufacturing and packaging from the UK. This is of course a brave move in terms of cost, however the quality and GMP standards are very high, plus the R&D and commercial teams can interact with manufacturing on a face-to-face and daily basis. This model is also very progressive and I would suggest possibly unique in Europe, compared to other pharmaceutical companies. It is also in line with the UK government's initiatives to focus on and further develop the manufacturing and life sciences sectors allowing the UK to attract inward investment and improve competitiveness versus other countries and of course increase employment opportunities in the UK.

Eisai is developing a unique presence in the Epilepsy therapeutic area with three branded epilepsy products already on the European market and we have recently submitted a Marketing Authorisation Application to the European Medicines Agency for a new first-in-class epilepsy product that was discovered by the company in the UK in collaboration with University College London. The plan is to have this product manufactured and packaged here in our European Knowledge Centre in the UK.

Eisai recently launched Halaven for patients with breast cancer in the UK. What are your expectations for this product?

G.H.: First of all I would like to mention that Eisai achieved a remarkable milestone with Halaven in that we managed to file Halaven for regulatory marketing authorisation in all three major markets (Japan, Europe and the USA) on exactly the same day on 31 March 2010. This is an achievement that we are all very proud of. We launched Halaven in April 2011 in the UK. This was the first European launch market and the second global launch market outside of the US. This demonstrates that the UK remains a very important market for the pharmaceutical sector and we are collaborating with the various health authorities including NICE and the SMC within the UK, to ensure that patients receive rapid access to this new and important medicine for the treatment of advanced breast cancer. Additionally, we have launched Halaven in Germany and Austria, two other early launch markets in Europe, as well as in Sweden, Denmark, Finland and Norway. Halaven is an interesting story about perseverance. This Eisai developed product, has been in development for almost 25 years, but Eisai's belief in the compound has paid off and Halaven is the first product to be approved in Europe for the treatment of advanced breast cancer, with a unique overall survival benefit in these patients compared to other treatments. The principal investigator of the pivotal randomised controlled clinical trial is a UK based oncologist and the pivotal clinical research paper was recently published in the Lancet. As an industry we are expected to provide brand new drugs that are better than those which are already available and used in the market today. This is exactly what Eisai has achieved with Halaven. We have understood that the ultimate payer, the governments around Europe, are demanding this kind of innovation and we sincerely hope that they appropriately reward research-based pharmaceutical companies like Eisai for it.

Eisai has experienced some difficulties with market access in the UK as was witnessed with the legal battle with NICE to have Aricept, your Alzheimer's disease product revaluated for cost-effectiveness. What other challenges has the company faced in achieving market access considering the NHS preference for generics and how have you been positioning your products?

NB: Before I answer your question directly, I would like to inform you that my new role in Eisai will to act as the director for market access for all of Europe and not only the UK.

Market access in the UK is undoubtedly challenging because of the approval process of the National Institute for Health and Clinical Excellence (NICE). Over time, after many judicial reviews in which Eisai played an important role, that process has improved and has become more transparent. It is now a fairer process as a result, but it still remains a significant step for pharmaceutical companies. Because of the way the system works a company can only have a

single chance to gain approval for a product and can then only contest the decision through a legal appeal. Another issue is that NICE has not in the past reviewed every new product which creates a situation where prescribers are less likely to use a new product, simply because there is no guidance from NICE for it. NICE was established in 1999 and, after more than a decade, I think we now understand what they are looking for and can tailor our filings to their needs. However in many of the cases when NICE does approve a product it is not for the full indication that has been approved.

Beyond the initial appraisal by NICE there are also regional approval networks that decide if they will allow the use of the product in the different regions of the country regardless of whether it was approved by NICE. Finally the last barrier comes at the local level where hospitals and Primary Care Trusts (PCTs) also decide whether to include a product on their approved usage list. A hospital's formulary approval is therefore contingent on the decision of the PCTs they serve. At times there are multiple PCTs that commission a hospital trust and they all have to decide to allow a product on formulary, but if they do not all agree, then a product will not be approved for use at the hospital. As you can see it is a very complex and challenging system and has the potential to be an obstacle for the growth of the life science industry in the UK.

The new 2011 Healthcare Bill proposes to change the PPRS to a new value based pricing (VBP) regime that is supposed to provide greater benefits for pharmaceutical companies that have invested in R&D. What impact do you foresee this Bill will have on your UK operations?

NB: Whilst VBP is an opportunity to improve access to patients for new medicines it does have the potential to make patient access worse. It could make the process even longer than it already is and lead to a greater number of payers and decision makers having to agree on access to a single product. The VBP scheme will include committees that assess social impact, unmet need and disease severity as opposed to a single body that produces Guidance. As we understand it NICE will provide a recommended price range that represents the value of a product's innovation. This will then lead into a negotiation period with the Department of Health that will potentially lengthen the process, and only after that may approval for the product be given and then possibly only for England and not the other countries that make up the UK. One major issue is that demonstrating a product is cost effective does not necessarily then make it affordable to the NHS. Until the government resolves these issues then the VBP scheme potentially will only aggravate the situation of market access in the UK. In the future this could lead to a potential delay in the launch of new products in the UK versus the rest of Europe, simply because the prices assigned to our products will be lower than the reference price for the rest of the European region.

This situation however is not unique to the UK, with the increasing demands on health systems across Europe, many European countries are implementing various methods of cost containment. The question is how to retain a vibrant pharmaceutical industry in the region while at the same time making treatments affordable to the national healthcare systems that pay for the products.

The truth is that at this point we are not sure what the market environment in the UK will look like in the future. We can only assess based on the threats and opportunities that we can identify right now. It will take another 12 to 18 months to really see what the future of the UK healthcare system will look like.

The definition of value is something that still needs to be agreed upon across Europe and that is the discussion that we are currently having with governments. The other side is our responsibility as a company to work with the authorities and to seek agreement on the definition of innovation and the value that should be placed upon that.

As a Japanese company operating in the UK, how is your corporate culture reflected in your daily operations and what advantages does this bring you?

GH: Our philosophy as a company centers around the patient and this has been true for decades. We believe that if we keep focused on improving health for patients and on the benefits that healthcare provides for patients and their families, then all the many challenges and complexities of operating as a research-based pharmaceutical company in Europe are worth it. This is not only written into our company’s articles of incorporation, we also have a policy that requires all employees to spend a minimum of 1% of their working time with patients in order to experience what patients go through when they are ill. It makes us realise just how privileged we are to work in healthcare, to be able to make real differences to patients’ lives and to bring this perspective back into the working environment to try and develop new and better medicines and introduce them to the markets for societies benefit at large. This is what ultimately motivates all Eisai employees, to remain committed and optimistic and come to work every day, by understanding what a patient experiences and by trying to improve their lives.

Thinking down the line, what would you have liked to achieve for Eisai in the UK and Europe in five years’ time?

GH: We would like to become entirely independent and not have to rely on other pharmaceutical partners to establish our footprint throughout Europe. In the meantime we want to introduce our own new pipeline drugs into the European markets, while successfully adapting to the challenging environment of healthcare and particularly to the austerity measures that most countries are

facing and will continue to face over the next five years or more. We plan to do this by retaining, recruiting and developing the best talent within the company in order to face the interesting and challenging times that we live and work in. Furthermore, we would like to see the successful operation of our European business as if it were the “United States of Europe” despite all the differences. For example, in the future I foresee that pharmaceuticals should have a single price strategy and that we should sell the same product at the same price in all European markets. If we genuinely think about and focus on patients, then it doesn’t make sense to have product delays and lack of patient access across Europe primarily because of price. I would therefore welcome more constructive win-win collaborations with the various governments across Europe. I see our role as a research-based pharmaceutical company is to help governments improve their healthcare systems and to bring new innovative products into the European markets to improve the health and lives of people; and that is all we want to do.

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