Interview: Seamus Fives – Chairman, BioPharmaChemical Ireland; Site Leader (Cork), Pfizer Ireland

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Chairman for BioPharmaChemical Ireland and Leader of Pfizer's two small molecule API manufacturing sites in Cork, Seamus Fives recounts his team's efforts to avert the closure of the Little Island facility through improvements in operating efficiency, and discusses how Pfizer is re-equipping their small molecule facilities to fit the needs of their current pipeline.

We understand that you have led a significant push towards efficiency at Pfizer's Little Island and Ringaskiddy facilities in Cork, successfully reversing a decision to close the Little Island site. How did this situation arise, and what have you and your team managed to accomplish over the last few years?

As many other pharmaceutical manufacturers and manufacturing facilities did, from 2010 through 2013, Pfizer faced multiple patent expirations for products made at our facilities here in Cork, including our cholesterol-lowering drug. Prior to the loss of exclusivity (LOE), we had made certain assumptions about the level of sales volumes we would be able to maintain; given the forecasted demand for atorvastatin that we expected to be manufacturing in Little Island, a decision was made that the site would need to close.

Despite these expectations, while approaching LOE, our team put a lot of effort into improving our competitiveness through operational excellence and the pioneering of new, second-generation manufacturing processes. As a result of these efforts, by the time our patent expired in late 2011, we had achieved very competitive benchmarks for cost and manufacturing performance.

Little Island is a prime example of how continuing to focus on competitiveness and adding business value generates business opportunities. In March 2015, Pfizer confirmed that due to continued increase in projected demand for a cholesterol-lowering drug for the foreseeable future, it was important to continue manufacturing atorvastatin in Little Island.

While this decision is mainly driven by the volume increase, Little Island's demonstrated commitment and continued excellence in the manufacturing fundamentals – Safety, Quality, Supply and Cost – was also a factor.

The global manufacturing environment is very competitive and our colleagues have been key in helping drive the fundamentals that have enabled us to achieve greater competitiveness during the past few years. The Pfizer sites in Cork have continued to demonstrate the highest levels of performance, flexibility and commitment.

How successfully have you been able to transfer learnings from the Little Island experience to other parts of the Pfizer organization?

Our Ringaskiddy site has also faced – and still faces – challenging LOEs, and as we did with our cholesterol lowering drug, we have introduced second-generation processes for the synthesis of other APIs as well. Many of the operational excellence systems and tools that we implemented in Little Island are also being used in our other sites.

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More broadly, at the global level, the pharmaceutical industry has clearly responded to price pressures and recognized the need to be more efficient in manufacturing. The changes have been visible at manufacturing sites across Ireland, with many manufacturers strongly embracing the continuous improvement ethos pioneered in the automotive industry, and exemplified by the Toyota way of manufacturing. Our efforts at Little Island constituted a part of this much broader shift.

In Pfizer's case, every day, we challenge our colleagues to find better ways of working and ways to optimize current processes. We see new efficiencies coming from such efforts every year and these improvements drive competition. Most critically, while we have been able to achieve competitive

benchmarks for costs, we have done so while maintaining exceptionally strong regulatory compliance; we consistently receive excellent results in FDA and HPRA (the Irish regulatory authority) audits.

As a whole, investment in the Irish pharma industry is trending towards large molecule facilities. That said, if we look at the small molecule side specifically, what are the main dynamics driving change and investment at present?

Across the industry, we have seen a major shift over the last five years in the types of products coming through the pipeline. Ten years ago, we were still in the blockbuster era where sales volumes could run into the 100,000s of kilograms for key products. Both of Pfizer's facilities in Cork were designed and built for such products: big buildings, big reactors, large numbers of people. For one particular blockbuster, we were manufacturing 200,000 kilos of API and 400,000 kilos of intermediates, for a total of 600,000 kilos of product – the physical logistics of handling this much product were immensely challenging.

Today all of these products are at or post LOE, and while we have a very healthy pipeline at present, the products themselves have much narrower target patient groups and the volumes are orders of magnitude lower. For example, one of our newest products, a treatment for metastatic breast cancer, requires volumes that will run in the range of 2000 to 4000 kilos at the maximum.

We recognized about five years ago that we did not have the types of technology and equipment that we would need to manufacture these products when it came time to commercialize them. As such, we submitted a proposal and received approval for a USD 30 million investment, which we used to completely refurbish one of our buildings. We removed the old large reactors used for manufacturing blockbusters and installed new equipment ideally suited to making smaller volume niche products.

This was an effective response to a very significant shift in our business, and my understanding is that many of the small molecule businesses in Ireland are seeing similar trends and adapting accordingly. There is some uncertainty, however, because it is not clear how permanent this shift is, and what sort of technologies are best suited to the challenges ahead. For instance, should we move towards continuous manufacturing or more flexible skid-type technologies, which could be even more portable?

Which approach has Pfizer taken?

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In the building we refurbished with that USD 30 million investment, we have thus far set up a kilo lab better suited to manufacturing smaller volumes of API, which gave us the opportunity to develop some skid technologies. A skid is in essence a modular system the size of a large table that you set up in a room to make a batch of a drug. When done, you take the skid out and replace it with a new skid set up for making a different product. Pfizer is very willing to invest in new technologies, but the investment will be made on the value proposition: we need to see the technology working reliably first, and know we have the right products to make use of it before we will invest substantially.

Considering Pfizer Ireland as a whole, how would you assess Ireland's overall impact on Pfizer's global value proposition?

Pfizer was one of the first pharmaceutical companies to establish itself in Ireland – in 1969 – and the company has a rich heritage of innovation and expansion over a forty year period. Pfizer has over 3,300 colleagues across seven locations based in Cork, Dublin and Kildare, with total capital investment by the company exceeding USD 7 billion. Pfizer's business interests in Ireland are diverse, including manufacturing, shared services, R&D, treasury and commercial operations.

Ireland is a leading manufacturing base for Pfizer globally, exporting to global markets. There is a manufacturing presence in Active Pharmaceutical Ingredients, Solid Dose Pharmaceuticals, Sterile Injectables, Vaccines and Biopharmaceuticals. Many of Pfizer's leading and newest medicines are manufactured for global export from Irish sites. The Irish manufacturing sites manufacture some of Pfizer's best-selling medicines across a number of therapeutic areas such as cholesterol reduction, urology, oncology and rheumatology.

Part of Pfizer's Worldwide Research & Development (WR&D) is also based in Ireland: the Global Biotherapeutics Technology group at Grange Castle was established in 2006 and is part of a world-leading protein drug discovery unit within Pfizer Worldwide R&D.

Perhaps most significantly, our role here at Ringaskiddy, and in coordination with Little Island, is to commercialize all new small molecule products that Pfizer is launching globally. We have significant R&D capabilities onsite, and our teams here work very closely with Pfizer's global research organizations to understand these molecules and develop the processes to manufacture them at commercial scales, as well as to continuously look for new and better second-generation processes to improve our competitiveness.

Looking forward a few years, what are your key goals and targets for Pfizer's Cork facilities? What's next?

Given the changes in the small molecule pipeline, I feel that we have adapted well to the shift in the business, but as we proceed, we must be constantly vigilant to ensure we have the right technology to make these new products. Pipelines change and many different technologies are currently being explored. At the same time, it is essential that we maintain our commitment to compliance and quality, never letting that waver while continually enhancing our value proposition through continuous improvement of our processes.

> “I am very lucky to work with a lot of people who clearly are among the very best at what they do.”

Regarding our teams, I am very lucky to work with a lot of people who clearly are among the very best at what they do. As such, it is essential that we offer robust career development opportunities within our organization because there is a lot of competition for talent; it is critical that our people feel supported and valued, and that they have enough opportunities to progress their career.

Despite first opening in 1969, if you walk around our Ringaskiddy site, you will see that the average age of our personnel is less than 40, yet many of them have very strong technical backgrounds and skills. I would very much like to see them have the opportunity to work on many more technically challenging processes and the newest technologies that are coming at us. I believe that our teams here at Ringaskiddy are very well positioned to implement these technologies into Pfizer’s global supply chain.

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