

Interview: Julie O'Neill Executive Vice President, Global Operations, Alexion Pharmaceuticals, Ireland

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15.09.2016

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Julie O'Neill, Alexion's EVP for Global Operations highlights Alexion's establishment of its Global Supply Chain headquarters in Dublin, Ireland, its investment in Athlone, her thoughts on the opportunities and challenges in the Irish pharmaceutical landscape, and her vision for Alexion.

Alexion first established a manufacturing presence in Dublin, Ireland in 2013 followed by the acquisition of the Athlone vialing facility for EUR 55 million in 2014. What was the rationale behind this expansion?

The original strategy behind the establishment was to centralize Alexion's global supply chain. Previously, as is the case in many organizations, we had pockets of excellence dotted throughout the world but as Alexion grew, it became increasingly necessary to centralize operations for knowledge transfer and efficiency.

My strategy, in conjunction with the rest of the Executive Committee, has always been to survey the risks and opportunities that Alexion faces. Many pharma companies begin with a very strong bias towards external manufacturing and CMOs, very understandably. However, you reach a pivot point where you need to reevaluate this relationship and make a decision: are we going to continue to work solely with CMOs on a third-party outsourcing strategy or look at developing in-house capabilities. That was where Alexion found ourselves: we looked at our portfolio of products and the supply landscape and we decided that we want to have balance. To ensure our supply chain security and to be ready for the future, we need to make investments in our internal manufacturing capability.

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The broad strategy of the global operations team is to have this balance in terms of our manufacturing capabilities.

Why has Alexion selected Ireland as a destination for roughly USD 750 million in manufacturing investment for the 2013 to 2019 period instead of say, Switzerland or Singapore?

We looked at every jurisdiction to see what best suited Alexion at the particular stage of our evolution.

The paramount criterion for us was the compliance record in the country. The Health Products Regulatory Authority (HPRA; formerly Irish Medicines Board) has spearheaded the compliance within the Irish pharma industry, from the 1990s on, the HPRA established high expectations for compliance with applicable regulations. There is the confidence that if HPRA has certified a site, the site will be certifiable by every other global regulatory authority.

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It also bears saying that this regulatory stringency is centered on HPRA's strong patient-centric focus. It is not regulatory burden for its own sake - it is safeguarding the best interests of the patients and ensuring that the industry retains a very strong focus on patient welfare. There was some initial fear when the precursor to the HPRA introduced this approach, about potential increases in costs and decreasing competitiveness, but I would say it has had the exact opposite effect. Doing things right the first time is far more cost-effective than having to redo it. The value of compliance is very powerful.

Another oft-overlooked element is the climate in Ireland: it is never really too cold or too warm, so utilities and infrastructure costs are quite stable. Incidentally, that is also why many technology companies like Salesforce, Google and Apple have established data centers here.

The overall business environment is supportive of multinational companies. IDA Ireland, the Irish investment promotion agency, have facilitated business entry, and there is a very robust but streamlined planning process, which works very well.

There is a very strong network - through BioPharmaChem, the innovators' association - and a spirit of collaboration being fostered within the industry. In general, as an industry, we do not discuss products, prices or employees but we do talk about areas of common interest. I can pick up the phone and reach out to any of my peers at any time. There is a strong commitment to open dialogue to ensure that we are aligned as an industry.

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There is certainly no lack of talent here, but there is also a lot of competition from pharma companies for these talented researchers and technicians. How do you ensure that Alexion remains an attractive company to work for?

The industry is also responsible for increasing this supply! I believe the pharma industry has a responsibility to develop, train and invest in its workforce. We have a strong internship program - we are trying to create an excitement about the overall pharma industry and of course, Alexion specifically. We want our interns to be our brand ambassadors when they go back to college.

That is also the beauty of working in manufacturing clusters: if you go back to the genesis of the pharma industry in Ireland, with the large investments in API facilities in Cork, expertise grew precisely because there was this community and movement of personnel between these companies. Clusters generate these spillover effects that advance the industry. That is another attractive aspect for Alexion; we are surrounded by other pharma companies and there is this huge exchange of

experience and expertise, for instance, with Pfizer at Grange Castle, BMS here, to name a few.

Your role entails the oversight of Alexion's global operations. What is your vision for Alexion in the next few years?

Globally, my role entails oversight and stewardship of molecules taken from research, right through the development pipeline, from clinical development into commercialization, distribution and customer operations. This means we are very closely aligned with our R&D team based in the US; my team itself is located all across the world.

As a company, Alexion focuses on life-changing therapies for ultra-rare diseases. Our EVP and Global Head of R&D, Dr. Martin Mackay has said: "we are in the business of transformative therapies irrespective of modality!" My responsibility is to ensure that, as Alexion moves into novel areas, we adapt our manufacturing and supply chain operations to the new demands of our active pipeline and acquisition targets. This is the inevitable challenge we will face and we cannot stand still; we must look to adapt and do things differently.

Agility, flexibility and excellence – these are the three words at the heart of every discussion I lead at Alexion. IDA coined a phrase a few years ago: *the Irish mind is its raw material*.

It is undeniably an exciting challenge and it has already been incredible to witness the transformation at Alexion. Alexion was a single-product company when I joined in 2014. We have since added two more in the last year and also witnessed significant growth. We also have a strong pipeline and so we hope to have many more product launches over the next few years.

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