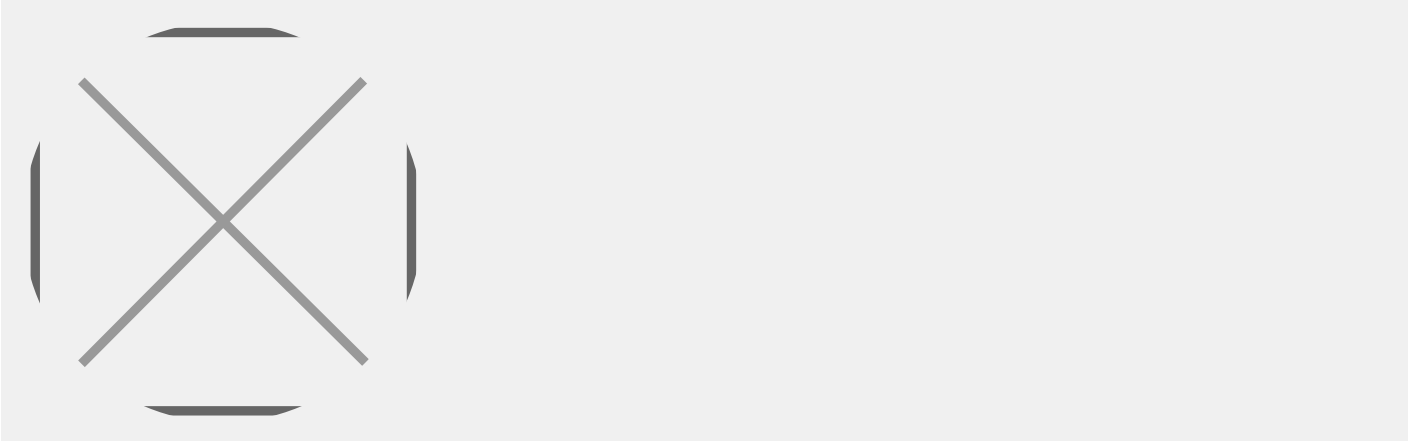
Interview with Matt Moran, Director, Pharmachemical Ireland (PCI)



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Mr. Moran, can you please begin with a brief introduction to Pharmachemical Ireland, its mission, and how it works to achieve its goals?

Pharmachemical Ireland (PCI) is an industry association representing the pharmaceutical, chemical, and biopharmaceutical manufacturing sectors in Ireland. Our raison d'être is to ensure that the regulatory and general environments are as favorable as possible for the industry.

We work to achieve this goal by interacting with government agencies such as the IDA, and regulators such as the Irish Medicines Board, Environmental Protection Agency, and Health and Safety Authority. We also represent our members internationally, where appropriate—for the most part, this means in Brussels, as Ireland is part of the EU and most regulation originates in Belgium. However, we are also linked to organizations in countries such as the US.

PCI also provides a networking service to the industry. We operate quite a large number of specialist working groups, which cover everything from pharmaceutical regulation through innovation, operational excellence, supply chain management, environmental health and safety, etc. These groups gather together experts from within the industry, and through them, we base our advocacy. We furthermore offer workshops and seminars, allowing people to interact and interchange ideas. The industry here is very collaborative, and works together very well.

Before we turn to the challenges of the present, and look towards the future, let's discuss a bit of the past. Historically, why do you believe the international pharmaceutical industry chose to invest so heavily in Ireland, ultimately making this sector one of the country's most important economic drivers?

The investment drive goes back to the early 1960s. At the time, Ireland—which is not a relatively new country—was exploring ways to move from what was essentially an agricultural economy, heavily protected by tariffs, to a market-focused system. The government established IDA Ireland, which is the industrial development authority. The IDA was given the remit of trying to attract

international businesses into Ireland. Given the size of the country, and the fact that we have very few raw materials apart from grass and rain, the agency concentrated on sectors that were based on intellectual property. They picked pharmaceuticals, chemicals, technology, and etc.

The IDA simply went out and sold the country—and they did so quite successfully. Through a number of incentives, they attracted names such as Pfizer and BMS to invest in this market. When the multinationals arrived here, they found that things worked quite well, and additional companies followed one after another. We saw an in-rush of companies from the 1960s through the 1980s.

The industry first brought bulk API manufacturing to the market. However, as time went on, they integrated additional stages of production, including finished products. Further still down the line—in part through our own advocacy as PCI—they moved to highly complex biopharmaceutical production.

Laterally, the industry has expanded operations to include development as well as manufacturing, aiming to create supply hubs for the sector.

Because the industry had a great experience with the performance of its initial infrastructure in Ireland, they have now re-invested. Several large multinationals now have a number of sites here. Some of this has been driven, obviously, my merger and acquisition—but much, as I have noted, is a result of re-investment.
Interestingly, given the current environment, which is quite challenging in terms of elements like the patent cliff and the difficulty of getting new molecular entities approved, we have nonetheless seen, in the last 12-15 months, approximately 1.5Bn EUR of re-investment into Ireland—either in the ground or CAPEX. The industry, though challenged, remains very important in the country. As we discussed prior to the interview, over half of Ireland's exports come from this sector.

The sector is also very high performance—the quality record is second to none. We receive very few warning letters from agencies like the FDA, and our companies stand on their reputation. The evolution of their operations has facilitated the development of quite a significant cluster of expertise in this country. Ireland is today the largest net exporter of medicines in the world.
PCI has been working on a strategy for the industry for the last couple of years, and our aim is to move the sector from manufacturing to 'manufacturing plus.'

When you say 'manufacturing plus,' do you refer to research activities?

Not very much basic research is done in Ireland. However, the industry is investing in product and process development—in other words, competencies that are close to manufacturing. This makes sense, given the size of the manufacturing base here. Producers want to enhance how their manufacturing activities function, affect cross-fertilization between manufacturing and development, and tighten the process between the clinic and product launch. They look to establish an end-to-end stream. In real terms, this may mean something like bringing a product from Phase II trials directly to launch quicker, more efficiently, and more reliably, while paralleling the regulatory track.

We are trying to position Ireland as the location of choice for the supply of all new entities (although unfortunately, there are fewer and fewer of those in the world, both in terms of large and small molecules). This drive fits well with the development of cutting-edge regulation, such as ICH 8, 9, and 10: QBD, and PAT. PCI actually hosts a specialist QBD and PAT working group.

We also do a lot of work with our members in manufacturing excellence, helping to implement techniques such as Six Sigma and LEAN. We look more and more to learn from other industrial sectors in that regard, because we do not believe the pharmaceutical industry has a great track record in the manufacturing excellence area. For instance, we are soon taking a number of our

members to Wales to visit one of Toyota's plants. We believe industries such as the airline sector, where Six Sigma came from, or cost-challenged industries such as the automotive sector, have much to teach us. Within our Innovation and Excellence report, we have identified several attributes that we believe a fit-for-purpose site of the future should have. The first of these is full compliance—which in our view is a given at this stage.

Even though most companies in the industry are multinational, the managers are mainly Irish. This allows them to develop the entire skills base of their operation hence bringing benefit locally and to the entire corporate network. Obviously, cost is very important. We must compete head-to-head with India and China—we have no other choice. Our labor costs are higher, though they are reducing Therefore, we must compete through smarter methods of manufacturing. This is the reason we put such focus on manufacturing excellence.

Another element that we often discuss is the seamless transition from lab to plant. If a company wishes to improve or enhance the process mid-stream or mid-patent, they should have that kind of capability on-site to make the process quicker and more reliable. People in laboratories also must be aware of what happens when their ideas wind up in a manufacturing plant—which is often not the case, because, say, they may be 3,000 miles away in New Jersey.

We have an opportunity to install such capability locally, and the companies are investing. MSD, for example, have put 100Mn EUR into such a facility next to their manufacturing plant. Pfizer have done it. Sanofi-Genzyme and GSK are in process.

In the introduction to the Innovation and Excellence Report recently produced by Pharmachemical Ireland, the association noted, 'The global pharmaceutical, biopharmaceutical and chemical industries face a challenging decade ahead. Major 'blockbuster' drugs are due to come off patent, and this will lead to a significant fall in revenues. Compounding the problem is the fact that new high-profile replacement products are not emerging from research in the same numbers as those that are going off patent. This has major implications for the industry in Ireland as many of these blockbuster drugs are produced here. Ireland depends heavily on the pharmaceutical sector which generated over 50% of Irish exports. Responding to the challenges facing the sector must be a national priority.' Can you discuss in greater depth your understanding of this problem, and how your member companies should respond?

Obviously, blockbusters are very high-revenue products.

And they are quite intertwined with the Irish economy—news sources have reported that patent loss on these products will palpably affect Irish GDP.

Because of the numbers, it will indeed affect GDP as well as GNP. If Lipitor is worth 12Bn EUR, and our national exports generate 130Bn EUR, of course we will feel the impact. That is a given.

What we have to differentiate is international perception—which is negative—versus what is actually happening on the ground. For Ireland, that is employment and economic activity. There is nothing that can be done about products coming off patent—it cannot be stopped. We must ensure that the industry doesn't go with it. The basis of PCI's strategy is to hold the industry here, ensure that the new molecules coming through the pipeline are made in Ireland, and ensure that companies will continue to invest capital in the country and bring high-end innovation to this market.

Ireland can keep the industry here by doing a number of things: first, by investing in its own research infrastructure, which is the task of organizations like Science Foundation Ireland. Second, by communicating with companies, and emphasizing that we understand their challenges and that the best place for them to conduct their manufacturing operations is still Ireland. When we launch such documents as the PCI, we do so in the US, in order to communicate out message internationally.
We must also try to replace as much of the revenue loss as possible. We know the revenue leaving, but it is impossible to predict the revenue coming in. We try to ensure that the high-end therapeutics are made in Ireland, because they are the most valuable. It has always made sense to make the most valuable therapeutics in a low-tax location.

We must maintain our capabilities. As supply chains become more scattered, and as companies cut headcount, quality has been challenged more and more. It is interesting to note that 483 warning letters from the FDA have doubled recently. Some of this is due to FDA administration, but much of it is due to the fact that companies are simply under pressure. Hence, the industry has to keep investing in the quality of its operations. I believe this is a prerequisite for Ireland, and I am glad to see that companies are committing. As Ireland, we can use quality as a reason to continue making things like APIs in this country—as opposed to making them in India.

Ireland can also potentially be a gateway from the East into the West—this is something we are exploring. For instance, as Chinese pharma companies eventually move outside of their own borders, Ireland is a great place for them to base some of their operations. We have an excellent reputation, and culturally, we are quite flexible—we normally get along well with people from most countries.

A recent article in the Irish press quoted David Gallagher, head of Pfizer's operations in Ireland. Mr. Gallagher said that because of the difficulties we see in the local Irish market—the austerity measures in the healthcare budget, and etc.—companies may think twice about bringing global capabilities here. What is your view on this issue?

Pricing and access is definitely an issue. While the PCI is not directly involved with the local market, it is something we pay close attention to nonetheless. We have communicated to the government that if Ireland wishes to be a location for the development of innovative medicines, it has to allow access for those same medicines. Negotiations are ongoing at the moment, and, particularly thanks to the efforts of our sister organization IPHA, we believe the government will respond appropriately.

The industry does not view any country in isolation, and our view is that Ireland must retain a position to the fore regarding access. We also must not go down a low-cost or a low-quality road, because that does not sit well with our innovation strategy and our approach towards attracting manufacturing and development into the country. We must be consistent.

As we have discussed, Ireland will never compete on cost; we can only compete on high-end—that is our niche. This mentality must inform all policies that we follow. There is a lot of austerity in this country at the moment, and there are cuts across the board. Nonetheless, there is a limit to how much we can cut.

Is the government doing its part to keep the industry's global capabilities here?

Generally, yes. The government understands what is at stake. The IDA is a great organization, and very effective at attracting inward investment from target countries. Local enterprises, on the other hand, are very well supported by Enterprise Ireland, the domestic development agency. The Irish

Medicines Board, while tough, has a good reputation—and complying with their requirements satisfies all of our global needs from a regulatory perspective. Science Foundation Ireland does a great job in building the basic infrastructure that surrounds the industry.

PCI does a lot of work in driving the interaction between the research community and the industry. There are many notable examples of such links: NIBRT, for instance, is a good example on the bioprocessing side. We have also been involved with an initiative known as a 'solid-state pharmaceutical cluster'—which clusters a number of universities that are in part supported by SFI and in part sponsored by the industry, and deals specifically with crystallography and morphology, and the interface between the API and the formulated product.
Ireland is a small place, so collaboration is easier here than in a larger country. People here collaborate by nature.

What will be the role of the pharmaceutical industry in returning Ireland to stronger economic growth over the coming years?

The only growth in Ireland is export-driven at the moment. The domestic market is flat, and will stay flat for some time. Given the fact that the pharmaceutical sector contributes so significantly to export figures, obviously our imperative is to mitigate the effects of the cliff, and ensure that as many new products as possible come through to replace losses and hold value—because this will be a significant aspect of the country's recovery.

I believe that without the pharmaceutical industry, Ireland would be quite a different place. Apart from the export numbers, there is the investment, the employment, and the knock-on effects. If you go to a town such as Westport in the West of Ireland, the main employer there is Allergan. Westport makes all of the Botox in the world.. Allergan helps to make Westport a vibrant place where people can find good careers as well being the best place in Ireland to live due to its natural beauty and strong sense of community.

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