

Interview with John Munson and Julie Murphy, Managing Director UK/Ireland, and Commercial Manager, Mylan

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Mylan embarked upon its first major international expansion program in 2007, after the acquisition of Merck KGaA's generic medicines business. How has the organization subsequently evolved in the UK/Ireland market and in Ireland in particular?

John Munson: In 2007, Mylan actually made two acquisitions: Matrix Laboratories, one of the world's largest API manufacturers and Merck KGaA generic medicines business. These acquisitions gave the organization vertical integration and the international commercial footprint that it was looking for. Mylan went from being a U.S.-focused company to a global player—something that was critical for our growth strategy.

The company saw Ireland as a key location for manufacturing and drug development. We have built a very robust operation in this market: firstly, Gerard Laboratories, a legacy Merck company and a major Irish employer, will produce about 2.7 billion doses for us this year. We are also looking to grow our respiratory platform and our institutional platform in Ireland. These are two key strategic drivers and Mylan has committed a great deal of resources in these areas within Irish operation.

From a generic medicines commercial perspective, Ireland is a relatively small market for Mylan. It is a small market because of its population size and because of the lack of generic medicines penetration in the country. Our commercial entity in Ireland is currently limited in scope but our wish is to deliver our mission of providing 7 billion people access to high quality medicine here at a local level.

However, the Irish government is now working to introduce generic medicines substitution at the pharmacy level. The sooner that happens, the sooner Mylan, the state, the economy, and the patient can benefit from the savings opportunities that generic medicines provide. We expect to grow our commercial presence as the market evolves.

So what did Mylan bring to our local marketing and sales operation in Ireland? Essentially, it gave us the opportunity to stay in the market, and to continue to provide access to patients to affordable treatments. Moreover, going forward, we will be in a much stronger place, because we are part of a global company. I believe that global companies are going to have an advantage over local entities because we have the resources to supply the Irish market and patients a bigger range of medicines. We have the capability to play in major growth markets like respiratory, biosimilars and injectables, which will again bring benefits and value to the healthcare system and patients.

There seems to be a broad push in Ireland toward greater generic medicines penetration—in addition to generic medicines substitution, the Association of Pharmaceutical Manufacturers in

Ireland's (APMI's) Fergal Murphy told Focus Reports that he looks forward to upcoming legislation that will establish generic medicines reference pricing. Mr. Murphy noted the striking fact that, even in the off-patent space, generic products have only about 50% market share in Ireland, with originator products often holding onto the market even after patent expiry. If this figure is set to grow to about 90%, as we see in a market like the UK, there seem to be strong opportunities for growth.

Julie Murphy: Firstly, I think that is important to clarify that generic medicines account less than 22% volume share and only 13% of the health medicines expenditure in Ireland.

Secondly we hope to double the volume share of Mylan to bring more generic medicines access to the Irish patients within the next few years. In my understanding, the government will look to set a target for generic medicines penetration in the overall market. This target will encourage General Practitioners (GPs) to prescribe more generic medicines and it will encourage pharmacists to dispense generic drugs when possible.

The state also plans to roll out an advertising campaign to encourage patients to use generic medicines and ask for generic medicines from their physician and pharmacist. For its part, the Irish Medicines Board (IMB) ensure that generic products pass through the exact same regulatory processes as originator brands, as such quality and efficacy are not an issue. There is an incorrect perception among the public that generic medicines may be somehow inferior, and this is a challenge that must be addressed through education. Generic medicines not only offer cost savings, but they also offer quality—the IMB, one of the toughest regulatory bodies in the world, make sure of that.

John Munson: As Mylan, we are incredibly focused on quality. With quality as our foundation, we hope to actively participate in the state's push to expand generic medicines presence in Ireland.

With that said, and while we hope that supporting legislation will be introduced quickly, we know that it is not just about the introduction of the bill, but also about its uptake in the market. Yes, the government will promote generic drugs, but as Julie mentioned, it is about patient acceptance, pharmacist acceptance, and prescriber acceptance. Without these elements in place, we will not be able to drive volume—and it is the volume that is afforded to generic medicines companies that allows them to produce quality medicines at a reasonable price, while also increasing the range of their portfolio.

From what I have seen in Ireland, even when the INN name is written on a prescription, the actual uptake of a generic product is only about 22%. That is because there are many products that have no generic medicines competitors, and because there is a brand bias in the market. To have more generic products in Ireland, there is a need to increase the volume opportunity. Hopefully, the bill will move the market forward, but it will be the implementation of the bill, and its acceptance, that will make the real difference.

The push toward generic medicines in recent years has made the Irish generic medicines market considerably more crowded. Actavis Ireland's Tony Hynds mentioned that for his company, Day One Launches are an integral competitive advantage. What is your own approach to competition and differentiation?

Julie Murphy: A key advantage for us is our portfolio. We have major plans to further expand this portfolio, and will look to capitalize on a number of large molecules set to lose patent over the coming two years.

Another differentiator for Mylan is our standing as a leading Irish employer. At the moment, we have 780 Irish employees, and an additional 500 are set to join us before 2016. That is a big, big selling point for the company. It is something that is appreciated and recognized by our stakeholders in the Irish marketing and sales operation, because after all, people buy from people!

John Munson: The portfolio is indeed critical. For instance, our specialist areas, and our antiretrovirals, are pillars for the organization. Meanwhile, as I mentioned, respiratory and biosimilars are also key drivers of our future and fundamental to reduce Irish healthcare expenditure. We are developing these products in Ireland via a huge production and R&D investment that shows our commitment to Ireland and high expectations on the generic medicines market.

Mr. Munson, prior to the interview, we began to discuss Mylan's new organization in Europe, and how this optimization has led to a new structure for the UK and Ireland marketing & sales operation. Can you expand upon those comments?

John Munson: We are looking to capitalize on the synergies between the UK and Irish markets. Ireland is a market in transition, and when all is said and done, we expect that its structure will be very similar to the UK's. The UK is a distribution market, with much larger volumes—nonetheless, in the UK, we believe that we already have experience with the challenges and opportunities that will characterize the coming Irish landscape.

In thinking about these changes, we wanted to ensure that the commercial team in Ireland had the best support possible. Rather than just expand the local team and try to buy in experience, we want to leverage the experience that we have already cultivated across Europe. We want to share that experience across our teams and deliver the value to patients through increased generic medicines access in local markets. .

The generic medicines industry is changing across Europe, and as Mylan, we need to change the game. We need to do things differently if we want to grow, and win. In Ireland, as elsewhere in Europe, we will win because we have the right attitude toward efficient manufacturing of pharmaceutical products, and because we will offer our Irish team a high level of support. By capitalizing on UK-Ireland synergies, we will improve our Irish marketing strategies, portfolio decision-making processes, supply chain processes, and overall effectiveness leading to greater success in the market, while keeping the patients and the sustainability of the healthcare system a key part of our commitment; it is all about doing good & doing well.

Generic medicines companies have greatly benefitted from the innovator's patent cliff. However, the good times may be coming to an end: the New York Times recently reported that while last year, 40 brand-name drugs valued at 35Bn USD in sales came off patent, this year, the value of drugs scheduled to lose their patents and be sold as generic medicines is expected to decline by more than half, to about \$17 billion. Should generic drug makers be concerned about a lack of good drugs to copy?

John Munson: I would like to answer to your question by saying that generic medicines companies do not simply copy, we also investigate and develop medicines. According to the European Commission sector inquiry report, generic medicines spend 7% of their revenues on R&D. In relation to the patent cliff it is something that we saw coming for quite some time. Indeed, our strategy 5 or 7 years ago was to prepare the global foundation that we would need to capitalize on the patent cliff's opportunities. However, even then, we were looking beyond the cliff. For this very reason,

we broadened our scope and identified value-added areas for further growth. Again, our injectable franchise is a great example.

Indeed, Mylan just concluded a 1.6Bn USD deal to acquire Bangalore-based Strides Arcolab Ltd.'s injectables business.

John Munson: Exactly. This acquisition demonstrates how focused we are on our pipeline, and how seriously we take its expansion.

We believe that our mission is to get high quality generic medicines to seven billion people around the world. Commodity generic medicines are very important to that mission. However, our next franchises are just as important. Antiretrovirals, for example, are already a strong driver for us in Africa, and we are now looking to bolster that business in Europe. And I must again go back to the injectables, and to respiratory! Biosimilars, too, are going to be a huge opportunity for Mylan. Our future growth areas will be more specialist—and as such we expect them to have less competition due to the costs involved in bringing such products to market. We expect, in turn, to derive a sustainable return on investment from these products while partnering with the healthcare system by bringing savings in this area.

Mylan seems to be continually strengthening its sourcing base in cost-efficient India. Are the benefits trickling down to the commercial organization?

John Munson: Our Indian operations are definitely a great benefit for the commercial business. However, it is also a significant advantage for us to have our own 20 industrial sites all over the world with strong presence in the U.S, in Europe, in Asia and in Australia. Cost is not the only factor for a generic medicines company: it's about reliability, and service. Having a flexible manufacturing operation, and a variety of manufacturing bases, means we can quickly adapt to the needs of different global markets, strengthening our levels of service, reliability, and customer loyalty. Quality is the most important differentiator!

Ms. Murphy, if we return to interview you again in five years' time, where will the Irish commercial business stand? You mentioned already that you would like to double your volumes—what are the other elements of your strategy today?

Julie Murphy: Firstly, I would like to emphasize the fact that the business will double in volume rather than value—because across Europe, volumes are going up and generic medicines prices are only going down. This is why it is so important to have a strong global company behind us, which can compete in the market despite pricing challenges.

As John suggested, going forward, every generic medicines player will have to focus on reliability. We have to be able to give the market quality medications at an affordable cost. We have to offer medicines across areas like respiratory, injectables, and biosimilars.

We need, moreover, to supply the market on a rolling basis, as it requires the medicine. For retailers, holding large quantities of stock is no longer attractive. As Mylan, we want to respond to their needs, and over the last five years, we changed our business model in Ireland: we introduced 'as-you-need' purchasing through wholesalers. There is no more need for the pharmacist to buy in

bulkâ??rather they enjoy twice-a-day delivery. Mylan was the first company to introduce this scheme in Ireland. Others have followed in our footsteps, but we were the first! We gave pharmacists a more flexible model to continuously supply the market and patients.

How would you describe Mylanâ??s company culture?

Julie Murphy: Mylan is about innovation, integrity, service, reliability and teamwork. We are passionate people, committed to do whatâ??s right, not whatâ??s easy. We work relentless to give people access to the high quality medicine they deserve. We are enjoying the support of the larger operation. As the commercial manager for the local market, I feel supported in Ireland, and I am delighted to have that backingâ??especially during this time of major change.

Do you feel excited about the market change? Or is it a great challenge to adapt?

Julie Murphy: I must say it is a bit of both. The transformation of the market is certainly exciting, but I would also call it quite â??stretching!â??

And yet it is good to be stretched. It is good to see results coming inâ??and because we have the support in place, we know we will achieve those results.

John Munson: Julie is in an interesting position in the market. When generic medicines substitution is introduced, we have little idea whether the volume effects will hit on day one, or a year down the line. In this sense, we have a lot of planning challenges. However, we have a highly flexible supply chain, which is a fantastic advantage. I believe we are well positioned to capitalize on emerging opportunities here in Ireland, as long as generic medicines become more widely accepted in the market.

I would also like to expand upon Julieâ??s comments regarding culture. Having looked after the UK exclusively until some months ago, I am new to the Irish organization. However, Irelandâ??s global importance as a manufacturing location stands out to me, and I believe that the fact that the country has been able to position itself as such an important player in the value chain is a testament to the Irish people. Ireland is a place that is extremely friendly and invitingâ??both for businesses and people. That is important to Mylan. It is important to those within the organization who have moved to Ireland from abroad, and it is important to the company from a local talent perspective. We do not take decisions to bring manufacturing or R&D to a given location lightly. The country, and the culture within that country, is extremely important.

As we begin to wrap up the interview, can you expand on your comments regarding Irelandâ??s positioning as a manufacturing and development location for Mylan?

John Munson: 90% of the 2.7 billion doses that we will produce in Ireland this year will go into Europe. As I began to mention earlier in our discussion, Ireland is hence a very critical location for our European business, and as one of our principal production geographies, it is integral to our flexibility as a drugs supplier.

We chose to manufacture in Ireland because we have the experience here, because we know the country, and because the state greatly supports pharmaceutical manufacturing and R&D. We know

we can be successful here. Ireland is a proven location for our industry to grow and do business.

Julie Murphy: I would also add that our specific location in Dublin affords us easy access to the seaport and airport, which is a great advantage from an exportation perspective.

What is your final message to our readers?

John Munson: As a location for pharmaceutical R&D, manufacturing, and packaging, Ireland is without a doubt one of the best—certainly across Europe, and, I believe, across the world.

On a local commercial level, Ireland is still a small market for generic medicines. However, patients deserve the opportunities that generic drugs afford them. As I said, Mylan wants to reach seven billion people around the world—and Ireland is a small market, but an important one. We hope, and indeed believe, that over the next few years, our commercial operations in Ireland will become as successful as our manufacturing operations.

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