Interview: Michael Kilkelly – Director, Recordati Ireland



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Ireland is home to Recordati's external supply operations and global in-licensing teams, alongside the API facility for one of the company's most prolific products; Director Michael Kilkelly discusses the advantages of running such operations in Ireland, beyond the many financial incentives.

In your opinion, why is Ireland such an attractive destination for multinational pharmaceutical companies?

If you look at the history of Ireland, regulatory compliance is one area, along with being an English-speaking country, that are often seen as primary factors motivating companies to invest here. Regulatory compliance is critical, as it possesses significant business risk, so Ireland's exemplary compliance track record is a main selling point to investors who want to mitigate these risks.

Quality risk is becoming more and more important as well, and quality risk management is a topic CEOs are now devoting more attention to. The Health Products Regulatory Authority (HPRA), formerly the Irish Medicines Board, is very strict relative to other regulators, meaning if you get a license granted by them it is good enough for the FDA in the US and most other regulatory bodies worldwide, which makes doing business much easier. Of course, the HPRA is also very involved in leading regulatory development to ensure we stay ahead and don't fall behind the FDA or other regulators. Thus far, the HPRA has focused on the regulation of pharmaceutical manufacturing; however, they are now strongly regulating wholesale and distribution.

I see this as a potential opportunity for Ireland to further enhance our role as a hub or center of excellence for the pharmaceutical industry. The HPRA is clearly interpreting European rules and norms on distribution very stringently, setting a very high standard, and all of the companies operating in Ireland have to conform to their expectations. While this puts a lot of pressure and responsibility on the organizations in Ireland, it also makes it relatively easy to do business with other countries where the regulations are not quite as stringent as those enforced by the HPRA. Ireland is already ahead of the game in many regards, and with progressive and rigorous public institutions like the HPRA and IDA driving us forward, Ireland will continue to be a very attractive place for the pharmaceutical industry to do business.

This competitive position will only be enhanced by the exit of the UK from the European Union, which will make Ireland the only English-speaking country in the European Union; at the same time, Ireland will always have a special relationship with the UK, and thus will be able to act as an effective gateway into both the UK and EU markets. At the same time, Ireland also has a strong relationship with the United States, both culturally and in terms of business. For example, some Europeans who have done business in Ireland are pleasantly surprised to find that Dublin airport has preclearance for US flights. Similarly, in terms of work culture, Ireland is closer to Boston in many respects than Frankfurt or Paris.

What aspects of this value proposition has Recordati leveraged thus far?

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Recordati's entry into Ireland started with an investment in a dedicated API facility for the manufacture of Lercanidipine, the molecule behind one of Recordati's most important blockbuster products, which came online in 2005. When the facility was being designed the intention was to launch this product worldwide, including in the US, and as such the excellent compliance track record of facilities in Ireland, strong regulatory environment and relationship with the FDA were all very attractive factors. Of course, Ireland's highly competitive corporate tax regime, as well as a capital grant from the IDA, certainly played a role in the decision to build this facility in Ireland and not elsewhere.

While this facility still operates today, the core of our activity is around the external supply operation which is based in Ireland, and deals with a lot of complexity. Our product portfolio and customer base are both growing consistently, and to support this growth we are currently constructing a new building on our site here in Cork. A key feature is that Recordati Ireland Limited has been granted a wholesale distribution license by the HPRA; this is a license granted under the

Good Distribution Practice guidelines, and is a relatively new designation for a regulator to grant companies. While such a license is not yet essential for pharmaceutical companies doing business internationally, over the next five years we will certainly see regulators around the world implementing stronger regulatory requirements, and having such a license will certainly be an asset that eases doing business in various markets.

What do you see as the key competencies that Recordati's Irish team bring to the table that can be difficult to find elsewhere?

Workforce flexibility is truly one of the greatest assets that we have here in Ireland, particularly in comparison to European countries where there is a lot more rigidity in the job market and employment law. Ireland also has a culture of people changing the direction of their career, which helps to develop professionals with a broad set of skills and experience, and by extension strong interdisciplinary teams that can unlock significant synergies.

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This variety of experience is a huge asset when you seek to develop a team capable of building or managing a complex supply chain. In-depth knowledge of many different facets of business is essential, and the communication across those functions must be smooth. I would say communication is in general a strength of the Irish from many angles. On one hand, culturally Ireland is nearly classless, as it is completely normal for say a judge and a farmer to chat over a pint at the pub – in this sense we are very much able to talk to anyone and everyone, which is a real asset when you must work with teams and colleagues around the world and be sensitive to their various cultural nuances. In another respect, one of the greatest advantages pharmaceutical professionals in Ireland have is the access to advice from highly experienced colleagues; I can pick up the phone and call three or four of my counterparts at other companies operating in Ireland for their analysis of a certain issue or solution to a particular problem, and get effective answers within a single afternoon. We collaborate and work together very well, and that is very much a strength of the Irish pharmaceutical cluster; competition aside, a rising tide will lift all boats.

You have mentioned that you manufacture Lercanidipine here in Ireland; what is this product and how was the Irish operation effected by the loss of exclusivity?

This molecule was invented by Recordati R&D department and is used to treat hypertension. It is a very good product in the sense that most hypertension drugs have significant side effects, water retention being a common. However, lercanidipine has a very low side effect profile, and was recognized early on as being highly effective product that would do well on the global market. As

such, Recordati made a decision to build a dedicated facility to produce lercanidipine, and given Ireland’s strong compliance culture, relationship with the FDA, and the package of financial incentives offered at the time, the decision was made to build this facility here in Cork.

Notwithstanding, starting in 2005 we began to manufacture lercanidipine here in Ringaskiddy. In January 2010, the patent expired; however, Recordati had a plan in place to mitigate the effects of this loss of exclusivity. The first part of this plan was to plug the anticipated revenue gap, so Recordati Ireland, on behalf of the group, began buying and selling new products under license. We initially saw a drop in volumes, however we simultaneously launched a lercanidipine combination drug that gave us a degree of exclusivity and was itself a very successful product. We also began entering new markets, mainly emerging markets in Asia, Latin America, and Eastern Europe.

As a result of these strategies, we have increased our sales volumes significantly since patent expiry, and in fact expanded our production capacity by 25 percent just last year. At the same time, we have developed a second generation process that is much more efficient, and lowered the cost profile significantly. With the improvements in efficiency have also come reductions in power and water usage, which actually led to Recordati Ireland Limited winning the European Energy Efficiency Award in 2013.

Our teams worked extremely hard to make this happen, and did so without any major capital investments, just old-fashioned process development and optimization. We are very proud to have bucked the trend in terms of patent expiration, and enabled the continued growth and success of this product beyond the loss of exclusivity.

Looking to the future, in which areas do you believe we will see the most focus, and what do you hope to accomplish here at Recordati?

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At an industry level, I see Good Distribution Practice compliance and serialization as the main challenges or drivers of change. Serialization is certainly an area where there is a lack of awareness, at some levels within different organizations, of the impact this will have on businesses in the near future. It is going to be an entire industry by itself the way things are going.

In terms of Recordati Ireland, I will continue to push for the development of the site. We have a large footprint, and have quite a lot of land as well. Additionally, all of the land surrounding us is owned by the Industrial Development Authority (IDA), meaning that we would be able to facilitate

any needed expansion. I will always be seeking more investment from Recordati, and my long-term aspiration is to see another Recordati facility built here in Ireland.

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