Interview: Dr. Leisha Daly â?? Country Director, Janssen; President, Irish Pharmaceutical Healthcare Association (IPHA), Ireland

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Dr. Leisha Daly, Janssen Ireland country director and president of the Irish Pharmaceutical Healthcare Association (IPHA) discusses her presidency and the conclusion of a four-year agreement between IPHA and the Irish government on the supply of medicine. She then highlights Janssenâ??s leadership in Ireland in terms of â??open-innovationâ?? and â??beyond-the-pillâ?? approaches, and her mission to make Janssen the most trusted company in Ireland.

Firstly, let us discuss your term as the President of the Irish Pharmaceutical Healthcare Association (IPHA), which comes to an end in September. What have been some of the key milestones?

It has been a great opportunity for both professional and personal development. The major milestone has naturally been the July agreement on the supply of medicines between IPHA and the Irish Government. The negotiations took up the bulk of my presidency: a year was spent either preparing for the negotiations or participating in them. Our first priority was to reach an agreement that would deliver a commercially-viable, substantial package that would meet the governmentâ??s expectations. This was a significant undertaking.

The changes that we have negotiated came into effect August 1. Notably, we have expanded the basket of countries that Ireland references, from nine to 15. We have also increased the existing government rebate from 4 percent to 5.25 percent in the community and 5 percent in hospitals, which took effect June 1. Furthermore, as biologics lose exclusivity and biosimilars become available, the prices of biologics will reduce by 30 percent.

The previous IPHA agreement saw the Irish pharma industry agree to the largest drug budget cuts per capita in European history. What does this new agreement mean for the industry?

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There will inevitably be immediate impact on pharma companiesâ?? revenues and also over the next four years as products reach the end of their patents and/or exclusivity periods. Some companies will be more affected than others. This is a difficult challenge but the agreement also offers the industry opportunities. The more important, long-term view is that this will enable us to bring new and innovative medicines to market much quicker. The Irish pharma industry needs to have the confidence of knowing that the money saved through the above measures will be reinvested in new medicines. It is not just about price reductions, but funding a sustainable growth in pharmaceutical innovation.

Currently, it can take up to two years for new products to reach Irish patients, which is unacceptable. Our other priority was to improve the reimbursement process and approach for new medicines. We wanted to give companies the peace of mind that Irish patients will receive new, innovative medicines in a much shorter time frame.

The pharma industry and the government in Ireland have typically had a very collaborative, open relationship, unlike some other European countries where there is a lot of tension between the industry and the regulators. Where do you hope to see this relationship progress?

What needs to be reiterated is that the pharma industry has been a huge contributor to the Irish recovery. Investment did not stop during the crisis. It is so important that we ensure that Ireland remains an attractive place to do business â?? and that the innovation happening in this country reaches the domestic market! Globally, five out of the top 12 products are manufactured here in Ireland, and we have a fantastic tradition of manufacturing, and increasingly, R&D investment.

Ultimately, I think this is the philosophy of the pharma industry. We are all about innovation, so we understand and fully support the introduction of generics and biosimilars when patents and exclusivities ends. On the flip side, we also need new medicines to receive market access as early as possible in order to generate the earnings needed to support this R&D. It has not been easy for the pharma industry in the past couple of years; we are not expecting it to be easy, but it should be easier than it currently is.

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Coming to Janssen Ireland, you have overseen this affiliate for the past eight years. What have been some of the main highlights during your tenure?

I am proud of the fact that we have brought Janssenâ??s EMEA portfolio to Ireland in its entirety. Janssen prides itself on its emphasis on innovation, and to be able to bring it all to Irish patients was a great achievement. The challenge with Janssen is that, precisely because we have such innovative, first-in-class products, under the Health Technology Assessment (HTA) process, it is more difficult to prove cost-effectiveness against older, off-patent products. Less innovative products

have an easier time, because they are compared with the first-in-class product. But we have worked constructively with the health authorities in Ireland to ensure patients have access to transformational medicines.

Our growth drivers here are in line with our global product lines. Globally, we have a wonderfully innovative pipeline in five key therapeutic areas: cardiovascular-metabolic, immunology, infectious diseases a, neuroscience and oncology. Products such as Stelara provide valuable growth while new treatments such as Imbruvica, a life-changing blood cancer treatment, and Trevicta, a new three-month injection for patients with schizophrenia, prove that we continue to innovate.

Finally, I am also pleased that we have improved our market positioning; we were the 9th prescription company in Ireland in 2012, and now we have moved up to between 7th and 8th â?? depending on the month! This is in line with our global rankings as well. We have plans to break into the top five, and I am very optimistic that it will happen in the next few years.

Jane Griffiths, Group Chairman of Janssen (Europe, Middle East and Africa), told us that Janssen was a â??trailblazerâ?? in the industry, highlighting the â??open-innovationâ?? model. Ireland faces a paradoxical gap in market access, because there is so much investment in the Irish pharmaceutical landscape but domestic market access still lags behind other European markets. How does Janssen Ireland deal with this?

We are probably one of the first companies to have a strong market access team, who are part of a wider external affairs function. We have recruited and built a team of health economists, for instance, because we know from experience that the National Center for Pharmacoeconomics (NCPE) prefers to work with people on the ground here in Ireland. The external affairs team also deals more broadly with government affairs and communications, and we take a more long-term perspective to dealing with the key stakeholders. It goes beyond simply putting a specific product dossier together and the short-term target of getting the product reimbursed. What we have done is work with government and patient stakeholders to understand their needs, to generate greater awareness and ultimately build that indispensable foundation of ongoing dialogue.

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Being part of the UK management team myself, I am familiar with other models of patient access schemes. We have a strong network across government affairs in Europe so that we stay well-informed about developments in other European countries.

Another one of Janssenâ??s pioneering initiatives is its â??beyond-a-pillâ?? approach. Here in Ireland, weâ??ve heard a lot about the great collaboration between both the public and private sectors, with a level of dialogue and trust perhaps not seen very often. What are some of the ways Janssen has engaged with patients and medical practitioners here to promote â??patient-centricityâ?? and better patient outcomes?

This is really a critical point for us, not just for Janssen, but for the industry as a whole. We are proud of the initiatives that we have introduced. Notably, we have a number of programs where we look at how we can promote better patient outcomes by focusing on the patient as a whole instead of just on the disease. For instance, we have programs that allow patients to receive their medicines or after-care at home rather than having to travel to a hospital. We have the â??Steps to Independent Living Programâ?? to assist people living with schizophrenia in their journey to recovery. We have also produced a very successful booklet for patients with prostate cancers, Man to Man: Irish Stories of

Hope in Prostate Cancer, which allows them to hear about other patientsâ?? experiences. These are all fantastic initiatives that reflect the full extent of the value that the pharma industry can bring to patients.

This is very much in line with the Department of Healthâ??s mission to treat patients at the lowest level of complexity: to keep them out of hospitals as much as possible and to treat them in the community. All these programs are precisely about engaging with patients without the need to have them in hospitals.

What are the challenges that you would say the industry is facing in Ireland?

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For instance, with the patient care programs that industry partners have initiated, it would be wonderful to see the Department of Health or the Health Service Executive (HSE), the Irish public health system, adopt them on a larger scale, especially if we have already demonstrated cost-effectiveness (in terms of saving on bed days, for instance). A key issue is funding and inadequate coordination between the different bodies that benefit from these programs.

Insufficient data is also a limiting factor, because we need to have robust data to demonstrate the value these programs provide. The healthcare sector is still very backward in terms of technology. It is heartening to see that the HSE has implemented a strategy to modernize the electronic patient records system. In this way, there can be more communication between hospitals and medical practitioners; only then can we understand treatment outcomes and program efficacies.

We also have a long way to go in terms of clinical research and development, which is an area that we are not yet very competitive in. We have a very strong set-up for clinical trials in oncology, through Clinical Trials Ireland, but in other areas, it is difficult to obtain approval from and coordinate between various institutions all across the country. For example, Denmark is not that much bigger than Ireland but they have a huge number of clinical trials. We need to streamline these processes to become more attractive.

Janssen has always sought to be at the forefront of the pharma industry globally. What is your vision for Janssen Ireland in the next few years?

Our aspiration at a European and Irish level is to be the most trusted pharma company. We have a team of 60 people in the commercial Janssen entity, while Johnson & Johnson (J&J) has almost 3000. We want them to be ambassadors for Janssen, J&J and the industry. J&J is a fantastic organization and we have so much to be proud of. We are looking forward to joining our J&J Consumer Health and Medical Devices colleagues in one office in the coming months. We hope this move will integrate our three commercial operations more fully.

Personally, I think we at Janssen â?? and the industry â?? need to do much more to communicate the true value of our products and our expertise. We need to raise more awareness of this and to engage our external stakeholders.

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