Interview: Oliver O’Connor – CEO, Irish Pharmaceutical Healthcare Association (IPHA)



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As a major innovative hub for (bio)pharma innovation, Ireland should be a place where innovative medicines are adopted quickly within the local healthcare system. IPHA director Oliver O’Connor explains the significance of the new 2016 IPHA agreement in contributing to a sustainable Irish healthcare budget and the delivery of innovative medicines to patients, highlights further room for progress for Ireland in terms of innovation access, and outlines IPHA’s main priorities for the next few years.

The big news for IPHA is the new Agreement, concluded on 20 July 2016, which saw a number of new initiatives projected to save Ireland EUR 785 million over the next four years. Can you provide an overview of this agreement?

The current drive towards limiting spending growth started following the post-2008 crash and ensuing European debt crises, and at that time, the pharmaceutical industry contributed to the stabilization of national finances by bringing a lot of savings. As in most countries, finding ways to support the early adoption of innovative medicines within a strict and sustainable budgetary framework has been a challenge here.

We understand that there are fiscal and budgetary constraints to be respected, and as such, IPHA has agreed to a new framework agreement that will help to facilitate the introduction of new medicines via two methods. IPHA members accounted for EUR 1.2 billion of the EUR 1.7 billion the

Irish state spends on pharmaceutical ingredient or ex-factory costs, so this agreement is significant. It will reduce the country's total expenditures on currently approved medicines by as much as EUR 785 million over the next four years, relative to what would be spent without this agreement and in absence of any policy interventions.

First, the agreement includes several mechanisms that will generate significant marginal-savings on older medications for the government, helping to create some headroom for reimbursement of innovative medicines, namely automatic price cuts and standardized rebates for medicines that lose exclusivity – as did the 2012 agreement – but with expanded scale and scope. Another specific mechanism for decreasing the price of biologic medicines is that when they lose exclusivity, the price will be decreased to 80 percent of the original price, and manufacturers will be required to pay a 12.5 percent rebate to the HSE or relevant agency.

The basket of countries used for external reference pricing will also be expanded from nine to 14, essentially the rest of the EU-15 countries. These prices will be adjusted, downwards only, each year to reflect price changes in the reference countries. Second, the pricing mechanism included in the framework agreement ensures that prices for innovative medicines being reimbursed for the first time will be relatively affordable to the state.

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Fundamentally, this agreement is a win-win: it provides, on one hand, a sustainable and stable financing and pricing framework for us, and on the other, significant savings for the state compared to the alternative of no agreement. Having a framework agreement is a positive thing for the relationship between the industry and the state, and it provides a good basis on which to develop further ties. Notably, this agreement is, unlike the 2012 agreement, explicitly with the wider government. Not only is the Health Service Executive (HSE), the Irish public healthcare body, and the Department of Health involved, the Ministry of Public Expenditure and Reform, and the Office of Government Procurement were party to the negotiations.

It was a tough negotiation but the resulting agreement portends well for the relationship between the industry and the state. What advantages does this agreement bring?

The main concern was access to new medicines; there needs to be a clear process for the adoption of innovative, new medicines in the Irish healthcare services, both in terms of assessment and reimbursement. Another important consideration was that medicines should be provided in a way both commercially viable for companies and economically sustainable for the state.

This agreement represents progress in many ways. The price realignment provisions instill confidence that prices will remain reasonable. The agreement length of four years, longer than the previous agreement's three, also provides a reassuring framework for business planning. For our members, having such an agreement on the supply and pricing of medicines in place is essential as it brings much needed predictability and stability.

An aspect that has gotten some attention is the inclusion of the Department of Health and the government in the reimbursement process for the first time. Under the new agreement, if HSE cannot reimburse a certain product, it can inform the Department of Health, who may then request for more funding from the government. This is intended purely as a safety net to catch new medicines that were not included in the healthcare budget formulation. Under the agreement, companies will provide an early horizon scan of new medicines at least six months before the year in which they propose them for reimbursement, so the Department of Health and HSE can incorporate them into their budgets. This provision allows the flexibility for a drug not originally included in the budget to be reimbursed under exceptional cases.

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However, it is important to also recognize that this agreement does not make any firm commitments regarding a specific level of spending, or in any way ensure innovative drugs will be reimbursed. This cuts both ways, as while there is no guaranteed budget for new innovative medicines, there is also no spending cap or risk-sharing provision.

Ireland has an international reputation for being innovative, in part due to the large scale investments from multinational companies (MNCs) in very innovative industries like biopharmaceutical manufacturing and technology. How deserving of this reputation is Ireland?

Ireland is a small country, which makes building relationships between stakeholders and functions a lot easier; this can encompass regulatory professionals, government policy makers, leaders of the manufacturing industry, and those working in public functions like planning permission. This interconnectedness is an advantage that also enables us to be flexible and adaptable, such that we can respond to changes and make decisions faster than might be the case elsewhere. These attributes certainly help facilitate innovation and have proven quite attractive for foreign investors.

The other aspect to consider is that government and industry have worked together successfully for many years to project a serious and attractive message internationally to potential investors. The content of that message has changed over time following debate between different

stakeholders, but it has always been unified. In fact, several foreign colleagues have commented on the fact that all of the various public and private stakeholders they interact with tend to express viewpoints and opinions that are very much in line with the 'Ireland Inc.' strategy. Ireland's innovative reputation has been carefully crafted through many years of collaborative effort.

On September 21-22, we will host the Biopharma Ambition conference in conjunction with BioPharmaChemical Ireland and the National Institute for Bioprocessing Research and Training (NIBRT). This conference will be a real testament to the fact that Ireland has reached the point where we are very much a part of the global conversation about where innovation in (bio)pharmaceuticals is going, and that Ireland is already a leading, innovative center of excellence for the global pharma industry. The individuals speaking at the conference from industry, regulatory bodies, and research communities are all leaders at the global level.

How innovative is Ireland in reality when it comes to the use of innovative pharmaceuticals within the national healthcare systems?

The Irish market for pharmaceuticals is relatively small. However, it is very important to the pharmaceutical industry in Ireland that the Irish public health service provides patients with good access to innovative medicines, and adopts new innovative medicines relatively quickly relative to European peers.

Traditionally, Ireland has been seen as a country with relatively early adoption of medicines versus European norms. However, over the last years, we have slid back to an extent. We do not yet have a good public policy metric of new medicines adoption or uptake in the public healthcare services, one that takes into account the amount of time between authorization and reimbursement finalization.

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The uncertainty over economic performance and the experience of the past eight years means that the government has been wary of guaranteeing any specific levels of funding. However, at present, IPHA's stance is that now that Ireland has a growing economy, there is the opportunity to invest somewhat more resources in health than was the case during the fiscal crisis when budgets were cut. Where innovators can clearly show proven value for money through HTA assessments, the government should embrace the opportunity to improve the quality of healthcare being delivered

to patients.

Ultimately, what we advocate for is greater coherence in Irish policies across every segment of the pharmaceutical value chain. As the Irish government advocates for the manufacture of advanced new biologics in Ireland, and the IDA seeks to frame Ireland as a highly innovative country internationally, then steps should be taken to make a place where innovation is supported and adopted within our healthcare system so Irish patients can have rapid access to these medicines, many of which are being manufactured here.

In a similar vein, as both the government and industry support research centers pursuing topics of relevance to pharmaceutical development, then there should also be better support and encouragement of clinical trials in Ireland, as we feel that Ireland and Irish patients would benefit from a greater volume or intensity of clinical trials.

One major point where we are constrained is the age and low quality of IT infrastructure in the Irish healthcare ecosystem. To properly implement new outcomes and value-based payment mechanisms, having access to very good real world data is essential to inform both ex-ante forecasts and ex-post assessments. Unfortunately, while Ireland is a small country and it would be relatively easy to record very high-quality population wide healthcare data, our healthcare system was starved of capital investment for IT systems for several years, and at present we do not have systems and databases capable of supporting these innovative financing techniques. The situation is improving however, as a modernization program is currently underway within the HSE.

With the Irish government beginning to plan its 10-year strategy for the Irish healthcare system, moving forward, what are IPHA's policy priorities moving forward?

Firstly, we are keen to monitor and measure the success of this IPHA agreement, and the metrics would be the numbers and speed of new medicines available to the Irish health services. We want to see that the agreement has visibly improved this, and that Ireland is a place where new medicines are adopted relatively quickly compared to other countries in Europe.

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More broadly, our priority is to do what is needed to ensure Ireland is an early adopter of new medicines, and that our industry is prepared for the changes that are coming at the global level. For both purposes, it is essential that Ireland invests in building the systems needed to better collect, manage, and analyze data, which will not only facilitate value based pricing and payment

processes, but also support efficacy assessments. Similarly, we would like to see better measures for the rate at which new medicines are adopted, and of the global value innovative medicines bring to the healthcare system by reducing costs associated complications, disease progression, or long-term care. Finally, we would like to see coherent policies towards pharmaceuticals across the industry’s value chain, with the Irish healthcare system engaging more strongly in clinical trials and strongly accepting innovative medical products, many of which are developed and manufactured in Ireland.

Fundamentally, the healthcare system in Ireland and Europe should focus much more on the outcomes in terms of reimbursement: funding should flow where there is value. This is also where the pharmaceutical industry can position itself and I would like to see the dialogue shift more towards the value of innovative products.

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