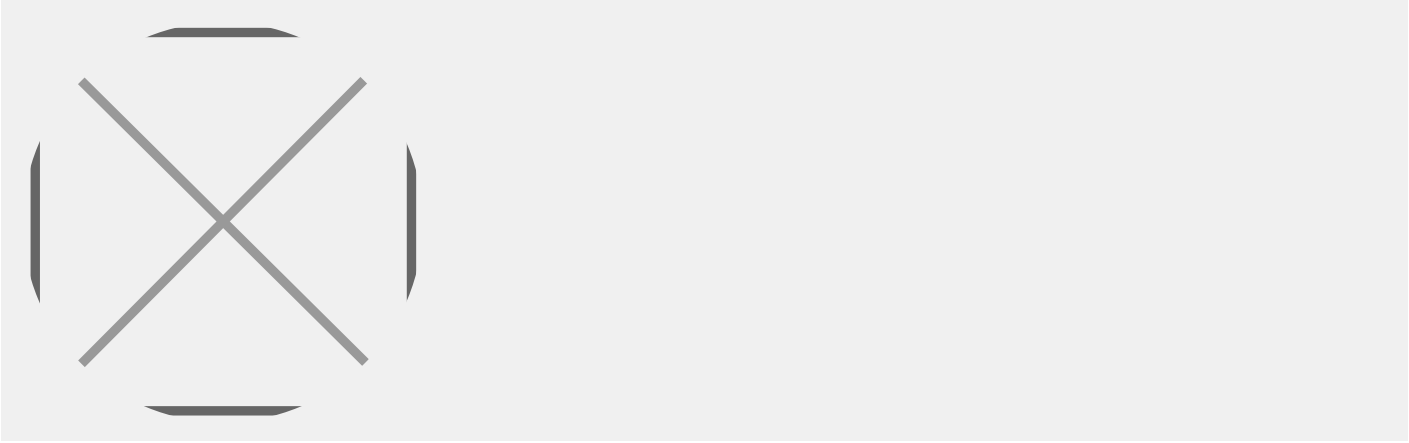
Interview with Anne Nolan, Chief Executive, Irish Pharmaceutical Healthcare Association



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With an evident recession and cost-cutting measures abound Ms. Nolan elaborates on the new plain on which pharmaceutical players have found themselves upon and how they have adjusted to the recent climate in Ireland.

Miss Nolan, you have been chief executive of the IPHA since 1994. How have you seen the Irish pharmaceutical environment evolve over these last two decades?

The environment has become increasingly difficult with each passing year. Our principal method of establishing the rules for pharmaceutical sales in this country has typically been to reach a formal agreement with the Irish Department of Health. We have had ten or twelve such agreements over the years, and each one became a bit tougher in terms of elements like supply contracts.

The last few years have been particularly challenging. Ireland is in a deep recession. The government has a severe lack of funds, including for pharmaceutical spending. Officials have approached us three or four times in the last few years asking us to please help them to realize savings. The industry has assisted in whatever fashion it could to provide additional savings over and above those already provided for by in our supply agreements. In the domestic market, since 2010, we have provided savings in the order of 19% of the total pharmaceutical market—which is quite considerable.

The environment will never be what it was before. It was easier to reach mutually beneficial agreements in the past; it is proving extremely difficult at the moment. It is very important for the industry to ensure that the government understands and appreciates our members' needs—we cannot simply bail officials out of the troubles in the healthcare system. The government has always been very supportive of the industry, and it is very important that they continue to be supportive.

We can always find some way of helping when we're talking. If we as an industry were the subject of draconian legislation that was passed without any dialogue, it would be much more difficult to do business in Ireland. Thankfully, this is not the case—the dialogue is there.

Many people have asked, 'The local market is very small; why does the industry care?' The industry cares because Ireland has always had a reputation as a good place to do business, and a good place to invest. The sentiment in the market, and the way in which the government will choose to support them, is very important in terms of sending the right message out to companies: that Ireland is a business-friendly environment that is supportive of innovation, and a country that particularly welcomes the pharmaceutical industry.

Is the government really sending this message, given the austerity measures? According to an IPHA report, "in the period 2006 to 2010, the industry delivered savings in the region of €300 million to ensure the State had the monies to fund new therapies. In 2010… the industry put in place arrangements to yield savings to the State of approximately €94 million in a full year. This saving is in addition to the savings of over €105 million generated, from the 2006 arrangements, in 2010. The industry further agreed to provide additional savings of €200 million for the State in 2011." What implication does this reality have?

The budget is indeed shrinking all the time. The industry was called in to see the Minister, we sat down, and we discussed. The difficulties the government was facing and we were asked to help. Recognizing the severity of the problems the industry agreed to step up to the plate.

In our view its always better for the dialogue to continue with a view to reaching agreement, rather than having any unexpected legislative burdens imposed upon us.

But what have the austerity measures really meant? Have companies had to significantly downsize? Have they stopped bringing innovation to market?

Companies have not stopped bringing innovation to Ireland. We like to believe that the government still supports innovation, and they are making the best of cutting-edge medicine available for Irish patients. We ran into a few problems earlier in the year, but we have resolved those through our discussions with the Minister for Health and his representatives.

We remain in discussion to develop a new mechanism for the future—for the next three-to-five years. Our discussions are more complex than they have been in the past; previously, we would have been able to resolve matters like this quite quickly. It is clear that there will again be substantial savings implemented, but we would prefer to have some market than none at all.

In terms of downsizing operations: the short answer is yes, budget savings—coupled with loss of exclusivity—have forced companies to make reductions. I cannot provide exact figures, because the effects are only just now washing through the system. However, anecdotally, we understand that there has been an approximately 50% reduction in field force throughout the market since 2010 we must however, and keep in mind that financial pressure is only one factor; the market is also changing—it is moving, for instance, from primary care to secondary care, so a different type of field force is needed. Market access is also a much bigger role for pharma industry staff at the moment.

In a recent report on the Czech Republic, Focus Reports found that market access was often called companies' greatest challenge. Is this the case in Ireland as well?

Yes it is. Getting products to the market is perhaps our members' biggest concern. In the past, we had agreements that made market access nearly automatic. Governments today look twice before they decide that they can afford a product. With mechanisms like HTA, automatic access is no longer feasible.

With this said, we are hopeful that we will identify a framework that will allow Irish patients access to the full range of today's available innovation—even if it comes under a different guise than it has in the past. As I have said, we are still talking and talking.

Another theme in the Czech Republic was that the government was often accused of being short-sighted in their budget cuts; industry members claimed that government officials saw only the high price of new drugs, but not the benefits that can be garnered in the social sphere. Would you make such a complaint?

It is always a challenge for governments to consider the bigger picture and join all the dots. Our government is no different, and austerity puts joining the dots under even greater stress. Officials are under pressure all the time to find savings—not just in the health bill, but in all aspects of state expenditure. Their challenges are immense. We like to think that we can help them, and find a mechanism to ensure that products can continue to reach the market.

Does a strong health economics framework exist here?

Yes. The framework has been in operation for 10-12 years now, and we have a dedicated pharmaco-economic center, which studies the value-for-money aspects of products coming on the market. It is a fairly robust system, and it is quite effective—it takes into account broader social

factors, as well as the cost of hospital stays, etc.

We see that the industry has a very robust manufacturing presence in Ireland, making this country one of the most important global hubs for multinationals. However, recently, an article in the Irish press quoted David Gallagher, head of Pfizer's operations, as saying 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 additional global capabilities here. What is your view on this issue?

I believe that if the government were not as supportive as they have been of the business in its totality, it would certainly send a negative signal to companies that Ireland no longer 'loves' the industry. We have no evidence at the moment that any companies are pulling out—for now. They still consider Ireland a good place to do business.

We all have to work to make sure that this mentality prevails, and the dialogue and partnership endures.

Do your members continue to bring increasingly complex stages of manufacturing here? Earlier stages of research?

They do. There a number of very interesting projects ongoing in Ireland. Years ago, we saw that investment was limited to basic manufacturing; today, the picture is quite a bit more advanced.

The industry will probably never conduct novel molecule discovery in this market. However, we do increasingly see companies investing in process research in Ireland. The plants that are in operation here are very high-tech, and additional competencies are being added. Companies have been here for 30 or 40 years now, and have a lot of experience in manufacturing products in Ireland and bringing them to the global market.

Our members are continuing to invest—whether it is setting up a clinical research function, or a regulatory department. One particularly interesting thing we see here is the early marriage of medical devices and pharmaceutical products; the market is becoming more solution-oriented rather than product-oriented, and the development of such solutions is taking place in Ireland.

On the subject of medical devices, in some countries, we see that there is a lack of fairness in value assessment, wherein drug budgets are always cut first, but medical devices go largely untouched. To what degree do you find a fair and balanced system in Ireland?

I believe the system is fair. When budget cuts are to be made and products are to be reduced, all of the suppliers in the system are called in—both pharmaceutical and medical device companies.

I will note that as the pharma industry, our business is a bit more structured; the medical device sector does not have the framework agreements with government that we have. This is both good

and bad—it means that we can point to the agreement if officials ask us to sacrifice too much; it also means that we are more visible. The government knows that they can turn to the IPHA in the case of budget troubles. The medical device sector is much more dispersed, and, in my understanding, negotiations are often done on an individual company basis.

Pharmachemical Ireland's Matt Moran commented that without the pharmaceutical industry, economic conditions in Ireland would be quite grim—certainly more so than they are now. Do you share this opinion?

Things are already quite grim here—but indeed, the situation would be even more grim without the industry. When Mary Harney was Health Minister, she called us in twice within the span of ten months, and I will always remember her words that Ireland is in a very 'bleak' place. Without the pharma business—particularly the export business—things would be worse.

The government is struggling, because last year, the net growth in the pharmaceutical business was negative five percent. The elements of growth within this figure were minus eleven percent on price, and six percent positive growth in volume. Unfortunately, because there is an increasing number of unemployed people in Ireland, the state is having to shoulder the cost of their welfare—this means that although we have delivered a substantial reduction on the price front, demand is going up.

Looking forward, what opportunities and challenges do you foresee for the next five years of Irish pharma?

In terms of challenges, we foresee difficulties in getting products to the market, and in keeping dialogue open with the government such that we can reach agreements about satisfying the needs of all patients.

Government has also recently decided to remove several products from the reimbursement list—products that they feel have been a bit of a question mark, such as fish oils and glucosamine certain —and we believe there may be more of this trend. The Minister for Health is in the process of putting a bill through parliament that will give him the power to look at product ranges and de-list. On the heels of this legislation, reference pricing will come in—as well as generic substitution.

We anticipate that the falsified medicines directive which is to come into effect shortly – will be a significant cost challenge for the industry.

Prices will be lower; volumes will be higher. As we discussed, this will be driven by the increasing unemployment rate.

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toward a universal health insurance model, and this will truly cause difficulties. Transitioning any large system always produces unforeseen effects.

And yet, within a five-year horizon, I believe that much of the difficulties will have washed through the system, and we will be in a more stable market. The major problem in Ireland over the last few years has been the pace of change: if we look at the evolution of the NHS in the UK over the last 40 years, we see that Ireland has experienced similar changes within a 3-5 year horizon. The situation is quite difficult, and we would like the government to take cognizance of that and allow people the time and opportunity to change—although the austerity does not make it easy.

On a positive note, the quality of our pharma employees is exceptional. As we have discussed, the multinational industry has brought globally-facing facilities and capabilities here—something we may not normally see in a country of our size. This has allowed our people to develop; and in a knowledge economy, people are everything.

Despite our current difficulties, and the challenges we have yet to face, Ireland is still an excellent place in which to do business. The government is still willing to talk to us and to listen to us, and therefore we can help each other. People should have confidence in the Irish state and its support of industry—for instance, our highly attractive corporation tax code is here to stay. The international pharma community should not loose confidence or loose faith, and they can rest assured that their businesses will be secure in Ireland—and indeed they will prosper and grow. There is a light at the end of the tunnel.

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