Interview: Dr. Lorraine Nolan – Chief Executive, HPRA, Ireland

"We are now facing a transition to become a global leader in innovation. The HPRA intends to play a key role in supporting that transition."

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Dr. Lorraine Nolan, Chief Executive of the Health Products Regulatory Authority (HPRA), the Irish regulatory agency, discusses the key objectives of the Strategic Plan 2016–2020, HPRA's active participation in European and international regulatory associations, and her commitment to positioning HPRA as a driving force to support Ireland in its quest to become the global hub for innovation.

You were appointed Chief Executive in January 2016. What new mandate were you given?

My appointment coincided with a new strategic plan, the HPRA Strategy 2016 – 2020, which I am responsible for delivering. Fundamentally, our role is to protect and enhance public and animal health through effective regulation of medicines, medical devices and health products and our strategy seeks to enable us to do this effectively and innovatively. We have achieved a lot in the past ten months alone.

A critical strategic objective of this 2016–2020 plan is support for innovation. One of the first things we did was to look at our internal structure. We have established a new department for Quality, Scientific Affairs and Communications, with a dedicated focus on the management of our scientific affairs to drive support for innovation across the HPRA.

We have also established an Innovation Office, which will be formally launched before the end of 2016. It will have a multifunctional role focused on the management of queries from innovators and early-innovators in Ireland to instill the knowledge of regulation early into the development cycle. This will enable both regulation and industry awareness of regulations to evolve in tandem with the development of new products. In this way, regulation does not become the barrier at the end of the process.

As a regulator, outreach is incredibly important, particularly with researchers and that of course includes academia. We intend to maintain extensive engagement with all R&D stakeholders, be they academics, start-ups, industry, funders or government actors. In early 2017, we are planning an information event to share information and enable cross sharing of learnings and insights.

This was a recurring theme at the BioPharma Ambition Conference held in Ireland in October. Ireland has been recognized as the global manufacturing leader for a few decades now, but we are now facing a transition to become a global leader in innovation. The HPRA intends to play a key role in supporting that transition.

What does it mean for a regulatory agency to be innovative?

Innovation is such a broad concept! We often associate innovation with advanced therapies like gene therapy or personalized medicine, but innovation is really anything that is clever and makes a significant improvement to patient lives. It could be a simple device that improves the delivery of a medicine.

Innovation is probably the single greatest challenge for regulators and the real difficulty is in managing its diversity. Patients are much more informed these days and they do expect, rightly, to have access to the most innovative and sophisticated treatments available. Regulators need to enable and not hold back innovation.

This involves a lot of horizon scanning, so that we have awareness of the new technologies and developments within the industry. This helps us assess and adjust our skills and competences to respond to new and innovative technologies. Regulatory frameworks also need to be capable of regulating these products. Innovation often pushes us into new areas, often into the borderline between health products or with clinical trials that do not fit in the standard model, and we are always mindful of our need to be agile and up to date with progress.

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What is the HPRA doing within this space to ensure that regulation does not become a barrier to innovation?

There is a lot going on in the regulatory space. The medical device regulatory system has historically been perceived as being more pro-innovation, and more flexible and adaptable in the pre-approval space. Regulators recognized that, because of the nature of some medical devices, there may be limitations in the extent of data that can be gathered through clinical investigations. As a result data needs to be gathered during both the pre-authorization and the post-authorization stages.

Within the EU, the pharmacovigilance legislation has really enabled regulation to be far more flexible. For instance, adaptive licensing very much mimics the medtech approach, where a product can be authorized early based on early clinical data, and subsequently, post-marketing data is supplemented to decide if it can be extended to more indications or patient populations.

What regulators are showing, I hope, is their capability to adapt and be pragmatic in looking at risk-benefit in a different way while still bringing forward safe and effective products. The HPRA has, for a number of years now, taken a blended approach to regulating medicine and medical devices. We now have a single department for pre-market authorization for both medicines and medtech, and a single department for post-market monitoring, and so on, to allow for this transfer of experience and expertise.

Perhaps interestingly for a regulatory agency, one of HPRA's new strategic objectives is also to generate more public awareness of its activities. What is the rationale for this?

The HPRA also wants to promote better information of our activities and our functions. We have a very diverse brief covering medicines, medical devices, blood and blood components, tissue and cells, and cosmetics, so it is very important that both healthcare professionals and patients have as much information as possible, both to promote compliance and to ensure the best outcomes for patients.

Patients are an important part of innovation; as the end user, their knowledge and experiences are vital. It is fair to say that in terms of engagement with patients, the regulatory community could be criticized for having been slow to engage. However, that is changing, and this has been led within Europe by the European Medicines Agency (EMA).

There are two categories of patients. Regular users of medication are naturally more likely to be aware of our role. There is a European patient initiative, the European Patients' Academy (EUPATI),

focused on increasing patient knowledge and awareness of regulation. This is managed in Ireland through an umbrella organization called the Irish Platform for Patients' Organizations, Science and Industry (IPPOSI). The HPRA has supported it through our involvement in the European platform, and a natural development as EUPATI comes to the end this year, is to continue the work of increasing patients' knowledge of regulation at a national level.

The second group is the broader public that are not currently taking long-term medication and therefore may have no awareness of the HPRA at all. A very exciting development for us this year has been our first ever public media campaign, the 'For the Full Benefit, Take Three Minutes' campaign. It intends to highlight the importance of reading the information that comes with medicines. It is surprising how often patients are not aware that the information leaflet exists, and the fact that even if they have read it before, they need to revisit it as it changes. This has been an important milestone for us this year.

An additional benefit of the campaign is to increase the HPRA's profile. We rebranded as an organization in July 2014, after being the Irish Medicines Board (IMB) for two decades, so it is important for us to increase awareness of our new name and our public health role among the general public.

For a small country like Ireland to have such an internationally respected regulatory agency is very impressive. How has the HPRA manage to build such a reputation?

There are many factors, but it boils down to our collaborative spirit. Collaboration is a fundamental principle enshrined within the organization and its activities.

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This is manifested in two ways. Nationally, we are part of the health sector in Ireland; while we do not provide healthcare, we have a very important role to play in facilitating the provision of quality health products to the system. Engagement with all the health service providers and a clear understanding of their needs is essential for us to be an effective regulator.

The life sciences industry is also an important stakeholder with whom we engage not just through regulatory activities like inspections and assessments, but also routine and consistent interactions, primarily led through the industry associations. We make provisions to have one-to-one meetings with companies. For instance, any company looking to set up manufacturing operations in Ireland engages with us very early on in the process and we have multiple rounds of discussion and assessments. We also offer qualification inspections to make sure that the entire process is smooth

and there is no showstopper at the end of the road.

While we do set the standards high in terms of regulation – and this is of course due to patient-centricity – it promotes compliance, which is of great value to the industry, not least in promoting further investment into the country.

Secondly, we have always placed huge value on participation in European and international networks. Health products are truly globalized, so the same issues related to monitoring the safety, efficacy and quality of them recur across the globe. There is huge value in terms of sharing regulatory resources and best practices.

We have a high level of penetration within the EMA. Notably, we hold significant positions on two of the main European health committees, chairing the Committee for Medicinal Products for Veterinary Use (CVMP) and co-chairing the Pharmacovigilance Risk Assessment Committee (PRAC). The HPRA is highly respected and trusted internationally, which enables us to influence key decision-making processes and have a voice at the table. It is resource-intensive but we see it as an important investment.

This goes beyond Europe; globalized products need a globalized regulatory approach, which may sound ambitious, but there needs to be greater convergence and sharing of best practices internationally. We are very heavily involved in the international networks. For instance, we are on the management committee of the International Medical Device Regulators Forum (IMDRF) and until very recently, we held the role of Vice-Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA).

What more needs to be done to promote further collaboration between national and supranational regulatory agencies?

A critical step is achieving mutual recognition on inspections between the US and European regulatory systems. It is a very important strategic goal for both sides, and from the outside, it seems like this should be fairly straightforward! When you actually get down to the details, however, there is a significant level of complexity to be grappled with. Different regulatory regimes, different product requirements, different focus – all of these barriers have to be overcome.

Globally, all regulators are struggling with the availability of inspection resources, and they recognize that working together and having greater regulatory reliance and ultimately regulatory recognition and co-operation is inevitable. Certainly in terms of the US and Europe, we are much

closer than we ever have been and I am very confident this relationship will develop further with time.

Outside of political negotiations, increasing collaboration and mechanisms for working together are also so important. Key examples include coalitions like the ICMRA and the IMDRF, which are essential to building co-operation and trust across the various regulatory regimes across the globe.

Speaking to the pharmaceutical industry here, the general sense is that while market access in Ireland has improved in the past few years, Ireland is still not leading the EU. Where do you see Ireland in terms of market access and what challenges have the HPRA identified as the most urgent?

To begin, we have to be realistic about the Irish market: it is small, which comes with a certain set of challenges. We have to work within that framework.

The HPRA is working constantly to drive that access to innovative medicines. We do recognize its importance, which is why we are placing so much emphasis on support for innovation. Our dialogue with the industry which has always been strong continues to increase. There are challenges, not least from a cost perspective – and of course, the HPRA has no input when it comes to pricing and reimbursement.

> “Access is as complex as innovation – it is as much about the infrastructure that exists when it comes to prescription and the monitoring of the patient’s health journey as regulatory activities.”

Access is as complex as innovation – it is as much about the infrastructure that exists when it comes to prescription and the monitoring of the patient’s health journey as regulatory activities. Connectivity of all the players within the health system, as the Health Service Executive and eHealth Ireland are currently working on, is hugely important. As e-prescribing and eHealth evolves in Ireland, the HPRA will play an important role in linking our data to these systems. We are committed to staying adaptive and flexible.

A final message?

It is a great time to be a regulator. There is a fantastic opportunity for Ireland to become a global leader for innovation, with the favorable government and policy background, the availability of skills and expertise and the increasing dialogue between firstly, academia and industry; secondly, pharma, biotech and medtech; as well as between the life sciences and tech industries.

The vision for the HPRA is to be seen as the organization that ultimately protects whilst also paving the way in supporting the industry and academic research communities in driving innovation.

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