Ireland Where Digital Health Thrives

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Navigating the regulatory pathway

Dr Lorraine Nolan, CEO of the Health Products Regulatory Authority, shares her thoughts on the importance of regulating digital health products and services

"The Health Products Regulatory Authority's (HPRA) role is to protect and enhance the health of patients and the public," says Dr. Lorraine Nolan, who has over 18 years' experience working within the biopharma sector. "Everything we do is built on this underlying principle."

As a state agency, the HPRA is responsible for regulating a range of health products in Ireland. The agency also participates at the working-level through the European Medicines Agency (EMA) and in the medical device space, through the European Commission.

It is vital to regulate digital health devices and solutions, to ensure they are as safe as possible and fit for purpose. "The core principles of regulation that apply to all products, apply also to digital health," says Lorraine.

She explains, "This involves having an appropriate design plan and vision for the product or solution, and carrying out a performance and clinical evaluation of the product. Then, ensuring that the manufacturing process of the product has been validated and this stays in a state of control."

"Once the product goes into the marketplace, traceability is required throughout the distribution chain. There needs to be an appropriate system in place for monitoring the performance of the products out in the marketplace." These traditional requirements, she noted, are more challenging to apply to digital health products.

Understanding the requirements

However, Lorraine says there is one difference to regulating digital health

products and that is “a call to be more adaptive and agile, in terms of how we work as regulators and the kind of information that we are evaluating and assessing”. This is due in part to the fact that these are cutting-edge, innovative technologies.

In recent years, the HPRA has established an Innovation Office, to provide regulatory support and advice to those developing innovative devices and solutions, from individuals to small and medium-sized enterprises.

“The aim is to help ensure that innovators have an understanding of the regulatory requirements that apply to a new product or device at an early stage of development. This can help to avoid potential regulatory issues at a later stage and ultimately lead to new products being developed and receiving regulatory approval quicker,” says Lorraine.

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“We have also commenced an outreach programme with higher education institutes and research centres, to further support innovation across the industry.”

What data means for regulations

Big data – captured across various devices such as wearables, as well as electronic health records – is hugely important in the healthcare sector today. However, this rapidly changing real-world data landscape means regulators need to evolve and change the way they access and manage data, to keep up.

“The EMA, in conjunction with the Heads of Medicines Agency (HMA), convened a big data taskforce, which has a number of recommendations to support the regulatory network and its evaluation for digital health products into the future. This involves looking at the skillsets agencies may need and how we can upskill on an individual level, as well as on a network basis.

“Attracting skillsets and talent has been a huge focus for us as an organisation and how we can further expand and develop in this area.”

How digital health is regulated

Lorraine advises that whether a digital health product is classified as a medical device depends upon whether it is intended for treatment or diagnosis. “And then there are additional requirements on top of that for software”.

“There is a segregation between some apps on mobile phones that simply gather health information, for example on how many steps you have taken today. These don’t necessarily qualify as a medical device.”

Lorraine adds the EU Commission is in the process of implementing a new framework for medical devices, the Medical Devices Regulation, which is scheduled for full application in May 2021. The new regulations will create a robust regulatory framework, recognised internationally, that improves clinical safety and creates fair market access for manufacturers and healthcare professionals.

“Under the new framework, software as a medical device will be up-classified and require certification by notified bodies,” says Dr Nolan.

Engaging the ecosystem with a vision

For any company developing digital health products or services, Lorraine advises having a design-and-development strategy, which is aligned to the regulatory process during every stage in the product development cycle. “This will enable early identification of the applicable regulatory requirements for the product, and facilitate sufficient planning.

“Generating and appropriately evaluating clinical data to demonstrate the clinical performance of the device and its safety is important too. As an organisation, we're very happy to engage with product developers and manufacturers to discuss the regulatory system and the requirements, and support innovators.”

Lorraine adds that Ireland is positioned very well in terms of innovation, “We have a very vibrant medical device and technology sector. It’s all about building proper ecosystems and ensuring that we interact with each other as much as possible across those ecosystems, so that we really can bring forward our ideas.”

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