



**Irish Pharmaceutical  
Healthcare Association**

## **IPHA Submission to Department of Enterprise, Tourism and Employment on National Life Sciences Strategy**

5<sup>th</sup> December 2025

### **Scope**

***Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production.***

***In your view, how broad should the scope of the strategy be?***

A successful strategy requires precision. For Ireland's National Life Sciences Strategy to deliver measurable impact and attract global capital, it must adopt a focused scope exclusively centered on human health. This definition aligns with international best practices and acknowledges the unique complexity of modern healthcare innovation.

Globally, the "Life Sciences" sector is defined by the convergence of biopharmaceuticals, medical technology (MedTech), and digital health. Leading jurisdictions—such as the United Kingdom and Denmark—explicitly separate human health strategies from broader bio-economy sectors. The same is seen in Massachusetts (US). By mirroring this approach, Ireland ensures its policy environment speaks the same language as international investors and regulatory bodies (EMA, FDA).

While the Agriculture, Food, and Marine sectors are vital pillars of the Irish economy, boasting world-class standards and significant export value we believe that they operate under fundamentally different regulatory frameworks, R&D timelines, and capital markets than human health.

To remain a global leader, Ireland's Life Sciences strategy must not dilute its focus; it must address the distinct ethical, clinical, and industrial realities of patient care.

To provide clarity for stakeholders and investors, we propose defining the "Life Sciences" ecosystem through three interconnected, health-focused domains:

- **Biopharmaceuticals:** Encompassing small molecules, biologics, and next-generation Advanced Therapy Medicinal Products (ATMPs), including cell and gene therapies.
- **Medical Technologies:** Covering medical devices, in-vitro diagnostics (IVD), and equipment essential for precise diagnosis and treatment.
- **Digital Health:** Leveraging health data analytics, digital therapeutics, and Artificial Intelligence (AI) to drive efficient care pathways and patient outcomes.

This focused definition allows for clear objectives that link Ireland's industrial strengths directly to improved health outcomes for its citizens, ensuring the strategy remains agile, relevant, and globally competitive.

## Objectives

***What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success?***

***For example: research and innovation, global competitiveness, patient outcomes, talent and skills,***

IPHA believes that the National Life Sciences Strategy should be the enabler for a future ready, dynamic ecosystem that nurtures and rewards scientific advancements, connecting cutting-edge research and innovation with patients through rapid adoption, thereby positioning Ireland as an early-launch market for innovative medicines and digital health technologies. It should also support Ireland's thriving manufacturing footprint, recognising the role global industry partners play as key contributors to this ecosystem.

The strategy should set clear, measurable objectives to secure Ireland's long-term success:

1. **Improve patient outcomes:** Ensure rapid adoption of innovative medicines and technologies, supported by sustainable reimbursement pathways.
2. **Clinical Trials Expansion:** Streamline approvals and harmonize processes to make Ireland attractive for clinical trials.
3. **Foster a vibrant innovation ecosystem:** Support science-driven regulation, incentivize R&D, and enable public-private partnerships.
4. **Retain strong IP protection:** Maintain a robust, predictable intellectual property framework to incentivize innovation and help close the gap with other global leaders to ensure competitiveness.
5. **Digital transformation:** Implement a national Electronic Health Record (EHR) system and enable responsible AI adoption in healthcare.
6. **Sustainability:** Balance environmental regulation with industrial competitiveness through proportionate, evidence-based approaches.
7. **A Life Sciences Council and Innovative Partnerships:** A permanent, high-level Life Sciences Council for government–industry–academia collaboration should be established. This would enable cross sector Innovative Partnerships to develop for shared benefit.

**Talent and Skills:** Continuous professional development and lifelong learning will be critical to keep pace with evolving technologies and regulatory standards. Emerging fields such as cell and gene therapy, personalized medicine, and advanced therapeutics demand highly specialized expertise. To meet this challenge, the Life Sciences Strategy must prioritize future-focused skills development. There is a growing need for STEM talent with strong capabilities in bioprocessing, data analytics, automation, and digital transformation—including AI, digital manufacturing, and Industry 5.0 competencies. Promoting STEM education among underrepresented groups, including women and minorities, is essential. This can be achieved through deeper partnerships with universities and technical institutes to co-create industry-aligned curricula, apprenticeships, upskilling programs, and work placements. Attracting global talent will also require investment in housing and infrastructure, while strengthening Ireland's international reputation as a leading biopharma hub that offers career growth, quality of life, and opportunities to make a meaningful impact.

**Make Ireland a leader for the life sciences at EU level:** The EU's legislative and policy framework is a significant determinant of Irish competitiveness and shapes our domestic eco-system to a high degree. It is vital therefore that Ireland uses its voice consistently and effectively to champion the life sciences sector in all relevant discussions at EU level, with the understanding that the future success

of this sector is closely aligned to Ireland's national interest. This will have a double effect – first of improving the overall environment for the life sciences in Ireland and across Europe, and second of sending a strong signal to the sector internationally that Ireland is a leader in this field. Specifically, this will require a conscious cross-Government approach in Council discussions on relevant policy files, working in consultation with a proposed Life Sciences Council.

### Opportunities and challenges

#### ***What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade that this strategy should address?***

Ireland's life sciences sector stands at a pivotal moment. Building on its global reputation for manufacturing excellence, the next decade offers opportunities to transform Ireland into a world-leading hub for innovation, digital health, and advanced research. At the same time, structural and regulatory challenges must be addressed to maintain competitiveness and deliver better health outcomes. The National Life Sciences Strategy should focus on leveraging these opportunities while mitigating risks.

### **Opportunities**

#### **1. Strong Manufacturing Base and Global Reputation**

Our heritage in innovation is key to Ireland's continuing success in the life sciences sector and in attracting new investments. Ireland's established leadership in biopharmaceutical and medtech manufacturing through continuity of policy over 50 years provides a robust platform for growth. By moving further up the value chain into high-value R&D, increased clinical trials, advanced therapies such as cell and gene, and digital health integration, Ireland can attract additional foreign direct investment and position itself as a launchpad for next-generation treatments.

#### **2. Access to EU Funding for Innovation**

EU programs such as Horizon Europe and future framework initiatives offer significant opportunities to fund biotech clusters, AI-driven healthcare, and clinical trial harmonization. Ireland should prioritize life sciences in EU strategic budgets and actively lead collaborative projects to strengthen its global competitiveness.

#### **3. Digital Health Transformation**

Accelerating the adoption of Electronic Health Records (EHR) and AI-enabled platforms will unlock precision medicine, real-world evidence generation, and predictive analytics. This digital shift will improve patient outcomes, reduce inefficiencies, and create a data-rich environment for research and innovation.

#### **4. Ireland's 2026 EU Presidency**

The timing of this strategy development coincides with a unique opportunity for Ireland to demonstrate leadership on the European stage. Ireland will hold the Presidency of the European Council in the second half of 2026. Launching a bold and ambitious National Life Sciences Strategy *before* the presidency begins would send a powerful signal of Ireland's commitment to becoming a European leader in this critical sector. It would provide a platform to champion innovation and shape the European agenda from a position of strength and clear strategic intent.

## **Challenges**

### **1. Regulatory Complexity and Slow Approvals**

Fragmented and lengthy approval processes for medicines and clinical trials hinder Ireland's ability to act as an early-launch market. The strategy must introduce streamlined pathways, regulatory sandboxes, and competitiveness checks to maintain global parity. Ireland needs to demonstrate progress towards faster patient access to new medicines and adherence to EU legislation on same.

### **2. Absence of a National EHR System**

Ireland remains the only EU country without a national EHR, limiting digital health adoption and data-driven R&D. Urgent investment is needed to implement interoperable health records and integrate with the European Health Data Space. Patients need greater access to their own information to make informed decisions about their health and care options. Furthermore, the integration of Artificial Intelligence, could enhance drug discovery, optimize clinical trials and improve patient outcomes.

### **3. Talent Shortages and Housing Constraints**

Skills gaps in STEM, data science, AI, and regulatory expertise threaten future growth. Coupled with housing shortages and high living costs, these factors impact Ireland's ability to attract and retain global talent, requiring coordinated policy action.

### **4. Risk of Overregulation**

The Strategy should reflect that regulatory requirements and industrial competitiveness are not mutually exclusive, and can be achieved through a transparent, science-based and structured dialogue. A pragmatic approach is needed to avoid the increasing complexity (and sometimes inconsistency) of environmental and pharmaceutical legislations undermining Ireland's competitiveness. Ireland should advocate for harmonized, pragmatic regulation that supports innovation while ensuring patient safety.

To secure Ireland's position as a global life sciences leader, the strategy must capitalize on digital transformation, EU funding, and Ireland's manufacturing strength, while addressing systemic challenges in regulation, infrastructure, and talent. A coordinated, future-ready approach will ensure Ireland remains competitive, innovative, and resilient in a rapidly evolving global landscape.

### **5. Policy Fragmentation**

The breadth of policy files which impact upon the life sciences sector means that relevant policymaking can easily occur in isolation, without a holistic view of its impact. A cross-departmental approach to policymaking is required going forward. Given its central role in overseeing the delivery of care to patients, and engagement with researchers, and with the med-tech and biopharmaceutical industries, the Department of Health will be especially critical to the success of any Life Sciences Strategy in Ireland.

## EU context

The European Commission recently published an [EU Life Sciences Strategy](#) aiming to position the EU as the world's most attractive location for life sciences by 2030. What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?

### **Aligning with European Ambition and Leadership**

The European Commission's ambition to make the EU the world's most attractive life sciences hub by 2030 is strongly supported. It is critical that Ireland's National Life Sciences Strategy is developed in close alignment with the broader European framework. This alignment is essential not only for maintaining competitiveness but also for accessing significant funding streams, influencing future EU policy, and leveraging pan-European initiatives to advance our domestic goals.

The EU Life Sciences vision is supported by three key strategic pillars. By aligning with these pillars, Ireland can leverage European momentum and resources to accelerate progress on its national objectives.

- 1. Optimising the research and innovation (R&I) ecosystem:** We need to leverage EU funding for Irish research and innovation projects.
  - The EU's drive to create a single market for clinical trials provides a powerful tailwind for efforts to strengthen the *local Irish clinical trial ecosystem* and increase participation in multi-country studies.
  - The significant EU funds being mobilized to drive innovation present a major opportunity for *local R&D projects* to secure investment, particularly through public-private partnerships.
- 2. Enable rapid market access:** We need to streamline local regulatory frameworks and adopt expedited pathways.
  - The EU's focus on simplifying regulation should serve as an impetus to modernize and *simplify local Irish regulatory frameworks*, reducing administrative barriers and speeding up the innovation pathway.
- 3. Boost trust and uptake:** Implement EHR and digital health solutions to improve patient engagement and outcomes.
  - The EU strategy's strong emphasis on harnessing AI and data can guide and accelerate *local digital and e-health developments*, including the urgent task of implementing a national EHR system.