IPHA Response to the EU Life Sciences Strategy Consultation

The life sciences sector is one of Europe's most important strategic assets, delivering innovative medicines and vaccines that are fundamental to the long-term health and wealth of the EU. Medical innovation continues to play an increasingly important role in maintaining the health of the EU's population and tackling unmet clinical needs.

The Irish Pharmaceutical Healthcare Association welcomes the European Commission's initiative to develop an EU Life Sciences Strategy to strengthen Europe's competitiveness, close the innovation gap and improve health care outcomes for patients. The strategy must actively explore opportunities for new partnerships and initiatives in emerging Life Science areas, reinforcing the link between a thriving industry, world-class research and manufacturing and equitable access to medicines.

The Draghi Report specifically identifies the pharmaceutical industry as a strategic sector for EU competitiveness. But in the last 20 years Europe has lost 25% of its global R&D investment. The US and China are increasingly attracting investment and production away from Europe due to more ambitious and dedicated strategies to drive growth. Similarly, Europe's share of global clinical trials has fallen from 25.6% to 19.3% in the last decade. Together with the Commission's Competitiveness Compass, which aims to close the innovation gap with competitor regions, a holistic EU Life Sciences Sector needs to focus on turning this tide.

Policy coordination: We are living in uncertain times with geopolitical and societal unrest and climate challenges. An EU Life Sciences Strategy must help deliver coordinated Life Science policies from bench to bedside, addressing the variability in the application of EU regulations. This coordinated approach should be supported by an EU Office for Life Sciences, which will be accountable for strategy implementation and gathering insights on emerging trends and implementation barriers.

Addressing Competitiveness Challenges: The current EU legislative landscape has created an unpredictable environment for the pharma sector. Several policy initiatives undermine competitiveness and are not pro-innovation. For example, the proposed revision of the General Pharmaceutical Legislation, which could potentially weaken IP and the incentives framework, comes at a time when we need to incentivize innovation into Europe. The EU should instead adopt a Competitiveness Tracker and Competitiveness Checks to assess policy impacts on the Life Sciences sector.

Timely Access to innovation by patients: To remain globally competitive, Europe must ensure faster, fairer access to innovation. An EU Life Science Strategy should foster structured high-level dialogue between industry, EU policymakers and health stakeholders to address access barriers, duplication and ensure that medical innovation is recognised as an investment. Create a harmonized EU clinical trials ecosystem via a single-approval model in addition to multi-country trials. This should support harmonized dossier reviews by National Competent Authorities and Ethics Committees across Europe, ensuring streamlined approval for multi-country clinical trials. (Source Report from Nordic seminar). There should also be investment in geographically strategic Centres of Excellence to bridge research and innovation.

Improve EU Competitiveness by Investing in the future workforce: Currently nearly threequarters of European science graduates choose to remain in the US after completing their doctorates. An EU Life Sciences Strategy should focus on investing in STEM education, upskilling and reskilling to build the future workforce and funding next-generation sustainable production.

Due to geopolitical challenges and global competition the EU's role as a hub for R&D has been impacted. A holistic EU Life Sciences Strategy encompassing everything from bench to bedside would benefit the economy but most importantly the healthcare outcome of patients.