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IRELAND

An Impactful EU Presidency

**Delivering for Ireland,
Strengthening Europe**

The American Chamber of Commerce Ireland

The Voice of US-Ireland Business

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Key Recommendations:

Simplification to drive European competitiveness:

- Ensuring the advancement of simplification measures is a foremost priority throughout Ireland's Presidency, with a focus on delivering consensus across Member States to address regulatory and compliance barriers.
- Prioritising the effective implementation of existing regulation, allowing such measures to 'bed-in' and for unintended consequences to be identified and addressed, rather than increasing complexity with new, layered obligations.
- Ensuring economic impact assessments are conducted for new legislative packages.
- Advancing measures to reduce administrative and compliance burdens for business, in line with the Commission's targets in this regard.
- Championing an open-market approach at EU level, that resists measures which are protectionist in nature.

Addressing fragmentation:

- Advancing measures which reduce fragmentation with regard to the national transposition of EU directives by Member States, supporting greater clarity for business in relation to compliance requirements.
- Reducing 'gold-plating' in Ireland's own domestic transposition of EU files, with a view to advancing competitiveness measures.
- Advancing the 28th Regime to allow for an optional, EU wide corporate law regime for businesses to reduce the administrative burden and support cross-border growth and expansion.

Tax sovereignty:

- Protecting the sovereignty of Member States in relation to taxation as a means of ensuring the EU is an attractive location for business into the future.

Third-party litigation funding:

- Advancing measures to provide safeguards in relation to third-party litigation funding, centred on oversight and transparency, for instance, through a Directive on minimum harmonisation.

A well-functioning Single Market:

- Promoting a fair trading environment for actors within the food supply chain, ensuring coercive commercial practices are addressed, under the Unfair Trading Practices Directive.
- Examining as to whether more tools are required to regulate territorial supply constraints, with consideration focused on impacts for the fast-moving consumer goods sector.
- Delivering modernisation in terms of public procurement for technology, with a focus on ensuring best value-for-money rather than lowest price.

The Digital Rulebook:

- Ensuring continued investment in physical and digital infrastructure to support Europe's digital future.
- Enhancing consistency in digital and AI regulation across the European Union.
- Developing regulatory frameworks that reduce the administrative burden on businesses, eliminate duplication of regulatory requirements, and provide greater clarity with regard to compliance.
- Advancing simplification of the digital rulebook.
- Introducing innovation and competitiveness mandates to existing and future regulation to advance competitiveness.
- Ensuring greater utilisation of impact assessments prior to the introduction of new regulation.
- Advancing the Digital Omnibus package, ensuring Ireland is a strong advocate for simplification.

Artificial Intelligence:

- Championing responsible AI development and adoption throughout the Irish Presidency.
- Prioritising simplification of regulations related to the digital and AI sectors, as part of a wider support for the simplification agenda.
- Utilising the International AI Summit to showcase Ireland's leadership in AI adoption.
- Supporting AI investment, connectivity and procurement in a manner which is not protectionist in nature, and is reflective of the open-market approach.

Cybersecurity:

- Advancing the cybersecurity elements of the Digital Omnibus, including the single entry point for incident reporting.
- Advancing harmonisation of incident-reporting obligations across NIS2, the Cyber Resilience Act, DORA and GDPR.
- Ensuring the Cybersecurity Act review is advanced in a manner that is transparent, and that certification schemes are developed in close collaboration with industry, and based upon technical criteria.

The Biotech Act:

- Advancing the Biotech Act with a strong pro-innovation focus to deliver clear incentives for biotechnology.

The Critical Medicines Act:

- Advancing the Critical Medicines Act in a manner that strengthens supply resilience through open trade, diversified supply chains, and competitive procurement while avoiding protectionist measures.
- Ensuring that localisation-based criteria are narrowly applied given the risk of reducing patient access.

The intellectual property environment:

- Ensuring Ireland utilises its voice to support pharmaceutical IP, Regulatory Data Protection and market exclusivity frameworks at EU level.

Clinical trials:

- Addressing timelines for the authorisation of clinical trials, in a way which maintains the integrity of scientific standards and ensures patient safety.

Preventative healthcare:

- Advancing measures focused on preventative healthcare and supporting vaccine uptake with measures to tackle communication challenges in relation to vaccine safety.

Horizon Europe:

- Delivering a well-resourced, ambitious successor programme to Horizon Europe, through the Multiannual Financial Framework 2028–2034 negotiations.
- Ensuring innovation and competitiveness are to the core of the Horizon Europe rulebook under FP10, with a view to simplifying access for business, academia and research.
- Support competitive state-aid reform and strategic investment in future industries, alongside a pro-innovation policy environment.
- Addressing barriers to RD&I funding including the application of eligibility restrictions under Article 22.5, particularly with regard to Cluster 3 (Civil Security for Society) and Cluster 4 (Digital, Industry and Space) funding calls, with a view to ensuring innovation within the EU is fully supported and businesses have clarity on eligibility and participation in relevant calls.

The Savings & Investment Union:

- Advocating for the SIU to enhance the EU's competitiveness, and as a means of delivering greater investment levels to support growth within Europe.
- Supporting retail investment in a manner which increases financial literacy and supports people in engaging with, and making informed choices on, the products available to them.

Talent & Skills:

- Ensuring Ireland utilises its voice to strengthen measures focused on lifelong learning and upskilling across the EU.
- Prioritising actions to address skills gaps, ensuring that the EU is best placed to grasp the investment opportunities of the future.

Foreword

Ireland's Presidency comes at a time when the EU's competitiveness is more important than ever. With changing geopolitical pressures, moves towards more protectionist policy approaches are becoming more commonplace. In the face of such moves, Ireland must utilise its Presidency to be strident in its defence of open-market, and free-trade policy approaches. By harnessing the Presidency, with a focus on advancing European competitiveness, Ireland can ensure that the EU enhances its attractiveness as a location for inward investment, business growth, and innovation.

It has been 13 years since Ireland last held the Presidency of the Council of the European Union. Much has changed in that timeframe. At this current juncture, Ireland's position as a core strategic bridge into the EU for US business provides a key platform for the country to showcase the benefits of an open economy, and the importance of the long-standing partnership underpinning the world's largest trading relationship. The opportunity in this regard is further enhanced given the concurrence between Ireland's Presidency and the 250th anniversary of the United States.

In advancing competitiveness, Ireland must communicate its own story. As a small, open economy, Ireland has developed a competitive economy on the global stage, which has attracted significant levels of foreign direct investment, fostered an ecosystem which supports collaboration between FDI and domestic business, and promoted the growth of indigenous business. Knowledge diffusion, labour productivity, and high levels of tertiary education attainment have become key tenets of the Irish workforce.

The impact of Ireland's approach is clear – there are over 1,000 US companies operating in Ireland, directly supporting 245,000 jobs in the Irish economy and further supporting 175,000 jobs indirectly. However, the collaborative ecosystem that has been delivered in Ireland, through its open economy, now sees Ireland, with 0.06% of the world's population, stand as the fifth largest source of foreign direct investment into the US, with Irish companies employing over 200,000 people across all 50 US states. For a small, open economy, this is a significant achievement, and with the key policy decisions to support the EU's competitiveness, this approach can be mirrored in the European context, further supporting Irish and EU indigenous companies to grow and expand on the global stage.

Simplification to drive European competitiveness

During its Presidency, it is vital that Ireland advances the European Union's simplification agenda as a means to deliver a more competitive Union for business – both those investing from outside the EU and indigenous European industry.

Progressing measures which focus on the implementation of existing regulation, rather than the introduction of new obligations, layered on top of existing rules, would allow for existing regulations to 'bed-in' and for any potential unintended consequences to be identified and addressed. Ultimately, this would provide greater certainty for business, enhancing the European Union's investment proposition, and giving clarity to small and medium sized businesses focused on growth and expansion.

The Irish Presidency of the Council of the European Union presents itself at a time when support for the simplification agenda is most necessary. Indeed, during its Presidency, Ireland must strive to maintain consensus amongst our European partners with regard to the importance of addressing regulatory and compliance barriers and tackling barriers to innovation. Ensuring that the advancement of simplification measures remains a foremost priority at EU level is of paramount importance, and will be critical in enhancing the Union's competitiveness on the global stage. This builds upon the Draghi report and the European Commission's Competitiveness Compass, which place simplification at the heart of restoring the EU's competitiveness.

In the delivery of new legislative packages from the EU, it would be beneficial to ensure that all such packages are accompanied by economic impact assessments to ensure measures support investment and innovation and recognise the realities of the business environment. Similar to the SME test at domestic level, ensuring that new legislative packages are examined with a view to reducing the administrative and compliance burdens which will be placed upon business is of the utmost importance. Indeed, the EU's SME and competitiveness checks provide a mechanism which can act as a foundation upon which to build economic impact assessments. In this regard, the Irish Presidency should advance measures to rigorously apply economic impact assessments, with a view to also advancing measures to achieve the Commission's targets of reducing administrative burdens by at least 25% for all businesses and 35% for SMEs.

During Ireland's Presidency, Ireland must showcase how it has realised the benefits of an open economy approach, and work to ensure Ireland's strategy is mirrored on the European stage. This will be key in pushing Europe to take an open approach, for instance with digital sovereignty, which supports balanced and proportionate regulation whilst resisting moves towards protectionism. Ireland's voice in this regard is more important now than ever before.

AmCham recommends:

- Ensuring the advancement of simplification measures is a foremost priority throughout Ireland's Presidency, with a focus on delivering consensus across Member States to address regulatory and compliance barriers.
- Prioritising the effective implementation of existing regulation, allowing such measures to 'bed-in' and for unintended consequences to be identified and addressed, rather than increasing complexity with new, layered obligations.
- Ensuring economic impact assessments are conducted for new legislative packages.
- Advancing measures to reduce administrative and compliance burdens for business, in line with the Commission's targets in this regard.
- Championing an open-market approach at EU level, that resists measures which are protectionist in nature.



Addressing fragmentation

As evidenced by many companies, fragmentation has occurred across policy areas with regard to the transposition of EU Directives into domestic law across the Member States. This has created significant administrative and compliance issues for businesses and has increased difficulties with regard to operating across the Union. Ireland must, during its Presidency, support measures to address fragmentation and provide greater clarity to business in relation to compliance. Such action will further enhance the European Union's attractiveness as a place to do business.

Indeed, looking to Ireland's own domestic transposition of EU rules, the Presidency is an opportunity for Ireland to lead by example by minimising 'gold-plating'. This would be positive in addressing compliance burdens for business, supporting domestic competitiveness, and utilising Ireland's voice as an advocate for competitiveness measures at EU level.

In addressing administrative burdens for business, the 28th Regime represents a positive initiative in this regard. This 'EU Inc.' proposal has the potential to bring great benefits in terms of streamlining obligations through the provision of an optional, EU-wide corporate law regime. During its Presidency, Ireland should work to advance this measure in a manner which will support businesses in growing across the EU.

AmCham recommends:

- Advancing measures which reduce fragmentation with regard to the national transposition of EU directives by Member States, supporting greater clarity for business with regard to compliance requirements.
- Reducing 'gold-plating' in Ireland's own domestic transposition of EU files, with a view to advancing competitiveness measures.
- Advancing the 28th Regime to allow for an optional, EU wide corporate law regime for businesses to reduce the administrative burden and support cross-border growth and expansion.

Tax sovereignty

In supporting the EU's competitiveness and ensuring its attractiveness as a location in which to invest and do business, it is of the utmost importance that the tax sovereignty of Member States is protected. Ireland, during and following its Presidency, must act as a strong advocate for sovereignty with regard to taxation.

AmCham recommends:

- Protecting the sovereignty of Member States in relation to taxation as a means of ensuring the EU is an attractive location for business into the future.

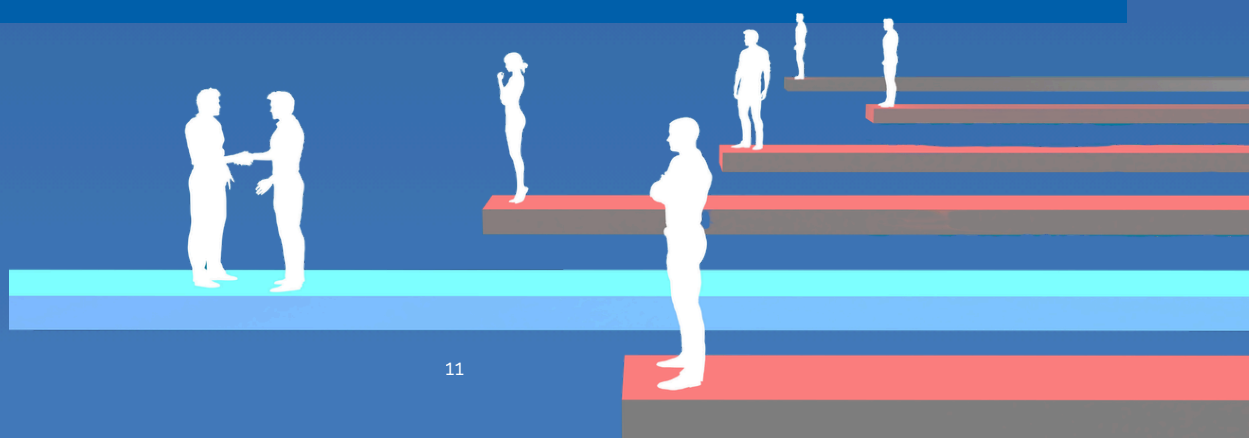
Third-party litigation funding

Action to prevent the unintended consequences of currently unregulated third-party litigation funding would be beneficial. Such measures would support competitiveness, providing safeguards and certainty for business, consumers and court systems, reinforcing the rule of law and enhancing the EU's attractiveness for investment. Ireland should progress work to achieve advancement of an EU Single Market that enables businesses to grow at scale, fosters innovation and strengthens open markets, furthering the EU's status as a premier global location to operate in.

Measures providing safeguards in relation to third-party litigation funding would be positive. By acting on oversight measures and transparency, the Presidency can support a responsible approach to third-party litigation funding regulation at EU level, for instance, through a Directive focused on minimum harmonisation.

AmCham recommends:

- Advancing measures to provide safeguards in relation to third-party litigation funding, centred on oversight and transparency, for instance, through a Directive on minimum harmonisation.



A well-functioning Single Market

Under the Unfair Trading Practices Directive, it is important that a fair trading environment is promoted for all actors in the food supply chain. As such, it will be important to ensure that coercive commercial practices are addressed. In this regard, it should be evaluated as to whether more tools are needed to regulate territorial supply constraints, with consideration given to potential impacts on the fast-moving consumer goods sector.

Further, implementing changes in public sector purchases technology represents an opportunity to modernise how the Public Procurement Act impacts on technological adoption. By working with European businesses and trusted global partners, to focus on ensuring the best value-for-money, rather than the best price, greater efficiencies can be driven in the public sector, resulting in the delivery of more effective digitalised services.

AmCham recommends:

- Promoting a fair trading environment for actors within the food supply chain, ensuring coercive commercial practices are addressed, under the Unfair Trading Practices Directive.
- Examining as to whether more tools are required to regulate territorial supply constraints, with consideration focused on impacts for the fast-moving consumer goods sector.
- Delivering modernisation in terms of public procurement for technology, with a focus on ensuring best value-for-money rather than lowest price.



Digital & AI regulation

Digital and AI policy must form a major focus for Ireland during the forthcoming Presidency of the Council of the European Union. Central to this, will be the successful hosting of the International AI Summit, meaningful progression regarding the simplification agenda, and driving innovation and competition through developing a future-focused policy landscape.

The digital rulebook

In keeping with the Draghi report, regulatory simplification will play a pivotal role in enhancing the EU's competitiveness for investment, building greater dynamism in the European economy, and unlocking future innovation within the EU. It is important that the EU first ensures that existing regulatory frameworks are fit for purpose and, while well intentioned, do not have the net effect of slowing innovation and investment in Europe.

This includes the need for reducing existing administrative and compliance burdens; providing clear compliance procedures and processes for businesses to engage with; eliminating regulatory duplications and tensions, while also clearly defining a hierarchy of regulations to ensure certainty and predictability; developing a simpler digital rulebook; and critically, placing innovation and competitiveness at the centre of all existing and future regulation.

These measures would mark a significant step change in the future of the business ecosystem in Europe, building on the progress made to date by the European Commission via various omnibuses, and supported by the Draghi and Letta reports. Further, this approach would enhance the operability and development of existing and forthcoming legislation including, the AI Act, the Digital Networks Act, the Digital Omnibus, Batteries Regulation, the Data Act, Digital Markets Act, and more.

The Digital Omnibus is the key tenet of the simplification agenda and must be a priority for Ireland's Presidency. This is a positive first step in terms of advancing measures to increase certainty for business. While strands, for instance with regard to broader data and cyber security remain under negotiation, Ireland must work to advance the Omnibus package and continue to use its voice to achieve further simplification in this regard.

Optimising the social and economic benefits of emerging technologies in the digital and AI sectors favours economies that are adaptive, agile and forward-looking. It is therefore imperative that Ireland, through its Presidency, sets an ambitious agenda to place the EU on the forefront of these policy fields, and that meets the needs of the public and business communities. In doing so, the EU can unlock new waves of innovation, drive start-up scalability within the EU, and ensure that world-leading talent and investment chooses the European Union as a premier location.

In terms of future regulatory development, greater utilisation of impact assessments that consider the effect of regulatory interventions on the competitiveness and innovation agenda first, can be a clear and positive step in developing practicable regulation, one that also sends a clear message to international investors that the European Union is committed to leveraging its strengths to significantly enhance its economic competitiveness and growth. Moreover, enhanced engagement with industry to test the implications of proposed regulations would prove to be a beneficial step in ensuring that regulations are clear, understood and operational from the outset.

Further, by ensuring regulatory functionality prior to implementation, these measures can limit the necessity for future omnibuses seeking to address issues within regulatory and legislative frameworks, which consume time and resources within the European Union, and prevents those resources being dedicated to other urgent matters.

AmCham recommends:

- Ensuring continued investment in physical and digital infrastructure to support Europe's digital future.
- Enhancing consistency in digital and AI regulation across the European Union.
- Developing regulatory frameworks that reduce the administrative burden on businesses, eliminate duplication of regulatory requirements, and provide greater clarity with regard to compliance.
- Advancing simplification of the digital rulebook.
- Introducing innovation and competitiveness mandates to existing and future regulation to advance competitiveness.
- Ensuring greater utilisation of impact assessments prior to the introduction of new regulation.
- Advancing the Digital Omnibus package, ensuring Ireland is a strong advocate for simplification.

Artificial intelligence

The Government's commitment to hosting the International AI Summit during the Presidency represents a significant opportunity to demonstrate Ireland's ability to lead the digital and AI debate in Europe and on the wider international stage. By showcasing Ireland and the EU's long-term commitment to responsible AI development and adoption, Ireland can position itself as a champion of digital and AI advancements in the European Union.

AI will shape the future of public services, work, and innovation across the European bloc and thus requires the EU to operate with clear focus and ambition, in order to fully realise the economic and societal benefits of AI. As a regulatory hub, Ireland is uniquely positioned to influence the development of related regulation within Europe and assist in developing a clear roadmap that puts Europe on the frontline of the future of the global economy. This will require continued investment in physical and digital infrastructure, consistency in regulatory approaches across the EU, ensuring regulation has flexibility inbuilt to match the rapid advancements of the digital and AI sector, and more.

It is essential that Ireland works to ensure Europe's focus with regard to AI is on adoption, capacity, and the opportunities and benefits that AI can bring both in societal and economic terms. Given the significant presence of world-leading companies in this sector in Ireland, huge opportunity exists for Ireland to showcase and advance the measures to support the deployment and adoption of AI. Ireland can, through its Presidency, act as a proponent for investment and connectivity with regard to AI. Further, Ireland must work to ensure that measures focused on building European capacity remain consistent with a non-discriminatory, open-market approach.

The review and development of a regulatory framework that allows businesses to grow at scale in Ireland and the European Union is of paramount importance to Ireland's Presidency.

AmCham recommends:

- Championing responsible AI development and adoption throughout the Irish Presidency.
- Prioritising simplification of regulations related to the digital and AI sectors, as part of a wider support for the simplification agenda.
- Utilising the International AI Summit to be hosted in Ireland to showcase Ireland's leadership in AI adoption.
- Supporting AI investment, connectivity and procurement in a manner which is not protectionist in nature, and is reflective of the open-market approach.

Cybersecurity

Ongoing efforts by the European Commission to streamline and strengthen the EU cybersecurity and data protection framework while reducing unnecessary administrative burdens on businesses operating across the EU Single Market are positive. The Digital Omnibus package is an encouraging step in this direction, and Ireland should work to advance this during its Presidency.

In particular, measures that build on the EU Cybersecurity Act, which strengthens the mandate of ENISA (The European Union Agency for Cybersecurity) and establishes a comprehensive cybersecurity certification framework for digital products and services are beneficial. A harmonised and risk-based approach to cybersecurity certification helps enhance trust, improve resilience, and provide greater regulatory certainty for businesses operating across multiple Member States. It is of the utmost importance that, as the Cybersecurity Act review proceeds, certification schemes are developed in close consultation with industry and in a transparent manner. Further, it is essential that such schemes are based upon technical criteria and do not introduce requirements which are sovereignty-based or non-technical in nature given that this would increase costs, create fragmentation in the Single Market, and ultimately have an adverse impact in terms of choice for users.

The European Commission's proposal to introduce a single-entry incident reporting mechanism for cybersecurity breaches is welcome. The creation of a unified reporting platform would enable organisations to meet their reporting obligations under multiple EU legislative frameworks, including NIS2, GDPR, and DORA, through a single reporting channel. This approach has the potential to rationalise overlapping compliance requirements, reduce duplication, and improve the efficiency of regulatory reporting processes while maintaining high standards of cyber security and safeguarding fundamental privacy rights. Such simplification is particularly important for MNCs that operate across several EU jurisdictions and must navigate complex and often overlapping reporting obligations. We call on all policymakers to continue pursuing practical measures that promote regulatory coherence, reduce administrative complexity, and support a competitive business environment, while ensuring that cybersecurity and data protection objectives remain fully protected.

However, a single-entry point is only a first step. In ensuring simplification for business, delivering coherent incident definitions, notification thresholds and timelines across relevant files will be key to ensure industry is not faced with divergent requirements behind the single-entry point.

AmCham recommends:

- Advancing the cybersecurity elements of the Digital Omnibus, including the single entry point for incident reporting.
- Advancing harmonisation of incident-reporting obligations across NIS2, the Cyber Resilience Act, DORA and GDPR.
- Ensuring the Cybersecurity Act review is advanced in a manner that is transparent, and that certification schemes are developed in close collaboration with industry, and based upon technical criteria.



Life Sciences

The life sciences sector plays an important role in the Irish economy, and the wider European Union economy. Indeed, Ireland is home to the operations of more than 90 pharmaceutical companies, 14 of the top 15 MedTech companies, and a growing base of clinical research activity. The implementation of pro-enterprise policies by consecutive governments has supported the development of the life science sector in Ireland. Emulating this approach at EU level would further support the development of life sciences on a pan-European basis, bring greater investment, facilitate indigenous growth, and enhance the RD&I ecosystem. This would also deliver significant societal benefits through the digitalisation of healthcare, and improved patient access to innovative medicines.

In this context, the delivery of a simplified regulatory landscape for clinical trials, for instance, must be amongst Ireland's priorities for the life sciences sector during its Presidency. This would support the EU in being a more attractive and competitive environment for research and innovation. Indeed, in supporting life sciences during Ireland's Presidency of the Council of the European Union, it is essential that files, including the Biotech Act and the Critical Medicines Act, are focused on enabling innovation whilst also tackling regulatory complexities and burdens.

It is of the utmost importance that the Irish Presidency works to deliver regulatory clarity for business, and advance measures which will both deliver better patient outcomes and economically benefit the EU. In this context, risks to competitiveness exist with potential changes to EU pharmaceutical legislation and global IP frameworks. As such, it is vital that during its Presidency, Ireland utilises its voice to protect pharmaceutical IP, market exclusivity frameworks, and regulatory data protection, ensuring that these items are not weakened or impacted in an adverse manner.

Further, the opportunity exists for Ireland to ensure a focus on preventative healthcare, which would bring widespread societal and health benefits to citizens and residents within the EU. Supporting measures which address communication challenges around vaccine safety would enhance vaccine uptake levels and coupled with investment in healthcare infrastructure and preventable health, Ireland can push forward actions which would have a real and tangible positive effect for generations to come.

The Irish Presidency of the Council of the European Union provides a platform for Ireland to advance measures which enhance the policy environment upon which the life sciences sector depends.

The Biotech Act

It is important that the Biotech Act is focused on supporting innovation while also addressing regulatory burdens and complexities. The opportunity exists to streamline the regulatory pathways for biotechnology and to create an enhanced environment for clinical trials. Ireland, during its Presidency, should advance the Biotech Act in a manner which works to make the EU a more competitive location for biotechnology R&D, manufacturing and commercialisation whilst ensuring businesses are not faced with additional levels of compliance and regulation.

In terms of the Biotech Act, it is essential that Ireland is committed to a pro-innovation position, ensuring that key measures are not diluted as the proposals progress through the EU's legislative process, and that meaningful incentives are delivered. This will be key in advancing the EU's competitiveness agenda in relation to biotechnology.

AmCham recommends:

- Advancing the Biotech Act with a strong pro-innovation focus to deliver clear incentives for biotechnology.



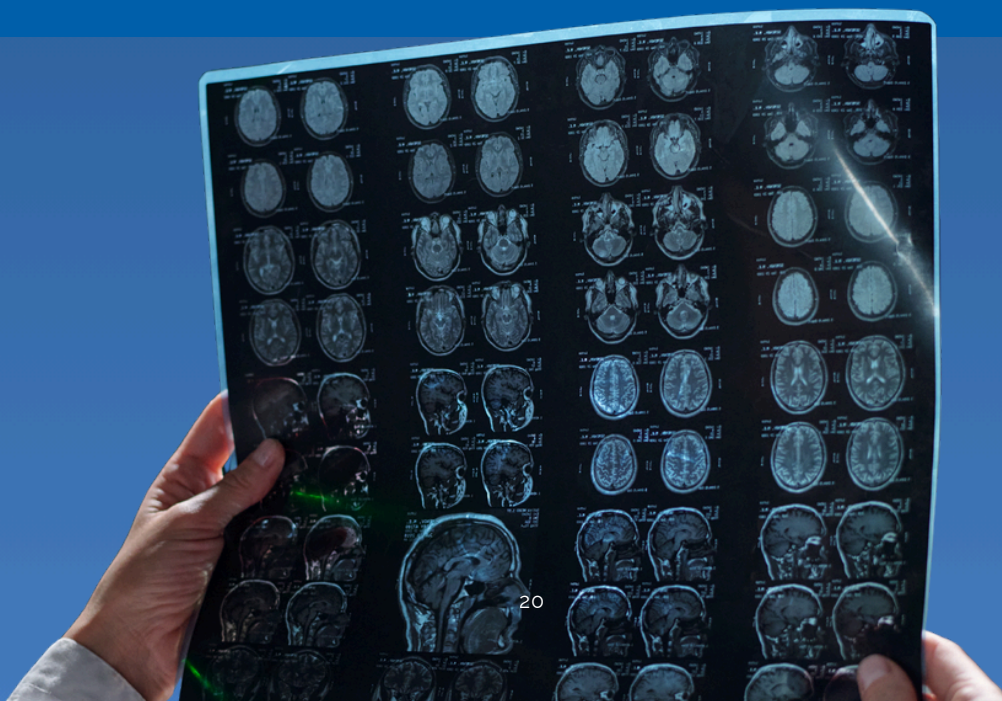
The Critical Medicines Act

Ireland must work to deliver the Critical Medicines Act in a manner which strengthens security of supply and the resilience of EU manufacturing and which does not undermine innovation. Diversified global supply chains, open trade and competitive procurement are the most effective means of delivering resilience and therefore such approaches should be promoted. As such, protectionist and 'buy-European' requirements should be avoided as they risk increasing costs, disrupting supplies, and compounding fragmentation within the Single Market. In this regard, in line with Ireland's core priority of advancing competitiveness, Ireland must continue to advocate for open-market and free trade approaches.

In terms of the Critical Medicines Act, localisation-based preferences would not be beneficial in addressing the causes of shortages. Instead, they would risk constraining patient access rather than enhancing it. Such an approach could be further counterproductive as it may result in reciprocal market-access pressures in other jurisdictions. As no single country manufactures the full range of medicines it depends on, and few medicines are produced in every market, security of supply is dependent on open and diversified sourcing, not on preference rules. In this context, Ireland must use its voice to ensure that localisation measures are narrowly applied.

AmCham recommends:

- Advancing the Critical Medicines Act in a manner that strengthens supply resilience through open trade, diversified supply chains and competitive procurement while avoiding protectionist measures.
- Ensuring that localisation-based criteria are narrowly applied given the risk of reducing patient access.



The intellectual property environment

It is critical that Ireland continues to use its voice at EU level to defend pharmaceutical IP, Regulatory Data Protection, and market exclusivity frameworks against being weakened. The broader point is that Ireland's stance at EU level should be an explicit part of a national strategy for the sector, rather than being settled file by file. The delivery of Ireland's national life sciences strategy later this year should support a whole-of-government approach with regard to Ireland's positioning on key EU files.

AmCham recommends:

- Ensuring Ireland utilises its voice to support pharmaceutical IP, Regulatory Data Protection and market exclusivity frameworks at EU level.

Clinical trials

A simplified regulatory landscape for clinical trials would make the EU a more competitive location for research, and that must be an outcome of the Biotech Act and the Critical Medicines Act. The Irish Presidency should work to address timelines for the authorisation of clinical trials in a manner which also ensures that patient safety, and the integrity of scientific standards are maintained. In doing so, innovation can be fostered, greater regulatory clarity can be provided for business, and measures which deliver better patient outcomes and economic benefits for the EU can be advanced.

AmCham recommends:

- Addressing timelines for the authorisation of clinical trials, in a way which maintains the integrity of scientific standards and ensures patient safety.

Preventative healthcare

In supporting preventative healthcare, the Irish Presidency should advance measures to address communication challenges around vaccine safety to support vaccine uptake. Further, investment in healthcare infrastructure and preventable health would deliver significant benefits for European society and the wider EU economy, whilst also supporting improved long-term health outcomes for patients and citizens.

AmCham recommends:

- Advancing measures focused on preventative healthcare and supporting vaccine uptake with measures to tackle communication challenges in relation to vaccine safety.



Research, Development & Innovation

In supporting research, development and innovation across the European Union, Ireland should utilise its voice to address barriers that have an adverse impact on RD&I within the EU, and to support measures which will enhance innovation within the Union. In enhancing and strengthening the EU's innovation ecosystem, the EU can become more attractive as a home for intellectual property and as a location from which to lead clinical trials. Further, this would bring significant benefits for citizens and residents within the EU, ensuring they can access new technologies and improved services for instance, as well as accessing innovative medicines which will improve health outcomes and enhance patient care.

Horizon Europe

The Draghi Report set out the case for a more strategic and innovation-driven Europe. In this regard, negotiations on the Multiannual Financial Framework will shape the EU's next programme focused on research and development. It is of paramount importance that Ireland, through its Presidency, works to deliver the next Horizon Europe programme as a well-funded and simplified programme as part of the tenth Framework Programme (FP10). Innovation and competitiveness must be at the core of the programme to support research, development and innovation taking place in Europe, and to ensure indigenous businesses and research centres are supported, through funding calls, in collaborating with multinational companies to strengthen the EU's RD&I ecosystem. Furthermore, in achieving both the Union's and Ireland's ambitions with regard to RD&I, Ireland must advocate against protectionist measures which are counterproductive to the delivery of a strong ecosystem.

Barriers and obstacles which limit participation in Horizon Europe calls can significantly limit the impact that the programme can have and can have adverse impacts in terms of the potential cascading benefits of thriving industry clusters. This is particularly the case with regard to funding opportunities under Cluster 3 (Civil Security for Society) and Cluster 4 (Digital, Industry and Space). Barriers in these areas include the application of eligibility restrictions under Article 22.5 Regulation (EU) 2021/695, which establishes Horizon Europe, allows the Commission to restrict participation in specific actions when strategic assets, autonomy or security are at stake. This creates uncertainty for businesses and organisations about eligibility (who can join, when restrictions apply), and can exclude some third party and associated countries from participation in relevant calls. As a result, this increases friction in partner selection and proposal design.

Over previous calls, such restrictions have increased, reducing the proportion of calls that companies, including US headquartered companies, can participate in. This can have a significant impact on the attractiveness of the EU for investment in RD&I. Further, in relation to complex IP & data rules, multinationals struggle to reconcile corporate IP strategies with Horizon exploitation requirements. In respect of financial & audit complexity, heavy compliance burdens deter corporate participation in large-scale applications. Therefore, it would be beneficial to ensure these barriers are addressed to support both Ireland, and the EU, as locations for research and innovation.

AmCham recommends:

- Delivering a well-resourced, ambitious successor programme to Horizon Europe, through the Multiannual Financial Framework 2028–2034 negotiations.
- Ensuring innovation and competitiveness are to the core of the Horizon Europe rulebook under FP10, with a view to simplifying access for business, academia and research.
- Support competitive state-aid reform and strategic investment in future industries, alongside a pro-innovation policy environment.
- Addressing barriers to RD&I funding including the application of eligibility restrictions under Article 22.5, particularly with regard to Cluster 3 (Civil Security for Society) and Cluster 4 (Digital, Industry and Space) funding calls, with a view to ensuring innovation within the EU is fully supported and business have clarity on eligibility and participation in relevant calls.



The Savings & Investment Union

The Savings and Investments Union (SIU) represents a key opportunity to significantly enhance the EU's competitiveness, alongside more integrated capital markets and a more integrated banking system. Both the Draghi and Letta reports identified capital market fragmentation as being a barrier to growth, while highlighting the level of investment that Europe requires to meet demand and to support growth.

The SIU will be a key enabler to support financing and investment within the EU, ensuring Europe is best placed to deliver innovation, business growth, and empower citizens to have a more secure financial future. However, it is essential that the SIU is advanced in a manner which ensures the EU remains open to international capital, and that barriers are not created with regard to inward investment as a result of deepening integration.

In terms of retail investment, it is key that this is delivered in a way which increases financial literacy to empower people to more confidently engage with financial markets. It is essential that this is also delivered in a manner which does not introduce complexity to the investment environment which could hinder people from engaging with the market or making informed choices on the products available to them.

AmCham recommends:

- Advocating for the SIU to enhance the EU's competitiveness, and as a means of delivering greater investment levels to support growth within Europe.
- Supporting retail investment in a manner which increases financial literacy and supports people in engaging with, and making informed choices on, the products available to them.



Talent & Skills

Talent and skills are essential to delivering competitiveness. Indeed, AmCham members identify Ireland's highly educated and skilled talent pool as its greatest competitive advantage. Given the demand for key skills, and changing demographics across the Union, it is vital that lifelong learning, and up-skilling are core tenets of skills development into the future.

Additionally, it is essential that action is taken to address and close skills gaps. Indeed, AmCham members have identified their greatest skills gaps as being in machine learning and AI, engineering, and digital and data. Ensuring the EU has the required talent pool in these key areas will be instrumental in ensuring the Union is best placed to attract future waves of investment to deliver new technologies and services.

Addressing skills gaps, and ensuring people are empowered to realise their full potential through up-skilling and lifelong learning will be essential in ensuring the EU is to the forefront of innovation in the years and decades to come.

AmCham recommends:

- Ensuring Ireland utilises its voice to strengthen measures focused on lifelong learning and upskilling across the EU.
- Prioritising actions to address skills gaps to ensure the EU is best placed to grasp the investment opportunities of the future.





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