Priya Life Science

INTELLIGENCE PLATFORM

PRIYA LIFE SCIENCE WHITE PAPER

High Expectations, Historic Opportunity

What Ireland's Rotating EU Council Presidency Can Deliver for European and Irish Pharma

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Executive Summary

On 1 July 2026, Ireland assumed the rotating Presidency of the Council of the European Union for the eighth time, its first since 2013, and arguably its most consequential ever for the life sciences. The six months of this Presidency coincide with a rare alignment of policy files that will define the European pharmaceutical operating environment for the next two decades: the final stages of the largest revision of EU pharmaceutical legislation in over twenty years, the Critical Medicines Act, the promised EU Biotech Act, negotiations on the post-2027 EU budget (including the successor to Horizon Europe), and the continued stabilization of transatlantic trade in medicines.

No member state has more at stake in these files than Ireland, and no member state is better placed to understand what is needed to get them right. Pharmaceuticals and chemicals account for close to half of Ireland's total goods exports, roughly €100 billion annually according to CSO trade statistics. The sector directly employs approximately 45,000–50,000 people across biopharma and chemicals, with tens of thousands more in supporting services, and nine of the world's top ten pharmaceutical companies operate substantial Irish sites.

This paper argues that the Irish Presidency represents a generational opportunity: not to advance narrow national interest (as the Presidency's role is that of an honest broker), but to bring Ireland's unmatched operational understanding of pharmaceutical manufacturing, regulation, and investment to the chair at exactly the moment Europe is deciding whether it wants to remain a global life-sciences power. A competitiveness-balanced landing of the pharmaceutical package, a funded and enforceable Critical Medicines Act, protected health research budgets in the next Multiannual Financial Framework, and continued transatlantic regulatory stability would together constitute one of the most valuable six-month policy windows in the history of the Irish life sciences sector.

1. The Moment: A Presidency at a Pivotal Time

The phrase "high expectations" has attached itself to this Presidency in Brussels health-policy circles for good reason. Council presidencies matter most when major legislation reaches its endgame, when trilogue negotiations between Council, Parliament, and Commission need chairing, sequencing, and the political craft to close. That is precisely the situation in the second half of 2026.

The general pharmaceutical legislation revision, the "pharma package" first proposed by the Commission in April 2023, has passed through the European Parliament's first-reading position (April 2024) and the Council's general approach (June 2025), and has been grinding through trilogues since. The Critical Medicines Act, proposed in March 2025 to address Europe's dependency on concentrated, often extra-European supply chains for essential medicines, is on a similar trajectory. The Commission has signaled a Biotech Act before the end of 2026. And the negotiations on the post-2027 Multiannual Financial Framework, which will determine funding for the successor to Horizon Europe, for EU4Health, and for HERA's medical countermeasures work, fall squarely within Ireland's term.

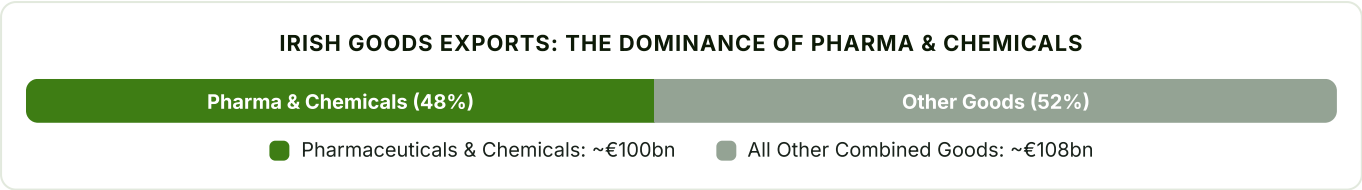
Ireland has historically punched far above its weight in the chair. The 2013 Irish Presidency is still cited in Brussels for closing more legislative files than almost any presidency before it, including the complex CAP reform and the €960 billion MFF deal. The machinery, the diplomatic muscle memory, and the reputation for pragmatic brokerage are all assets Europe needs now.

Deciding which files get Council time, which compromises get tabled, which trilogues get scheduled and at what tempo, ultimately shapes outcomes. A presidency that deeply understands how medicines are actually made, regulated, and supplied is structurally more likely to land workable legislation than one for which pharma is an abstraction. Ireland is that presidency.

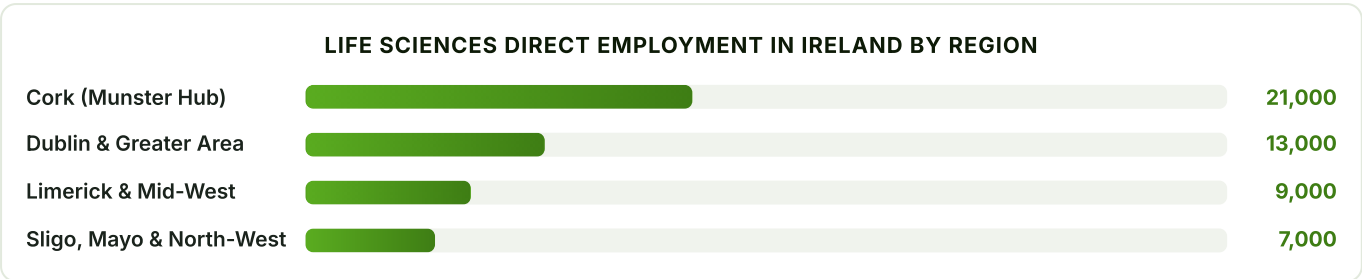
2. The Evidence Base: Irish Pharma by the Numbers

Any assessment of the stakes must start from the data.

Exports: Medical and pharmaceutical products consistently represent Ireland's largest goods export category, roughly €100 billion in 2024 per CSO figures, approaching half of all Irish goods exports. When the wider chemicals family is included, the share is higher still. Ireland ranks among the top three pharmaceutical exporters in the world in absolute terms, an extraordinary statistic for a country of its size.



Employment: Industry bodies place direct employment across biopharma and chemicals at approximately 45,000–50,000 people, with total employment supported by the sector (including contractors, engineering firms, logistics, and professional services) estimated at roughly double that. These are regional, highly skilled, and high-wage jobs situated across Cork, Limerick, Waterford, Mayo, Sligo, Dublin, Carlow, and Tipperary.



Investment Footprint: Nine of the world's top ten pharmaceutical companies have Irish operations across more than 85 sites. The past three years alone have seen major capital announcements, such as Eli Lilly's expansion in Limerick and continued MSD and Pfizer investment across their Irish networks, sustaining a decades-long pattern of multi-billion-euro capital deepening. Ireland is not a brass-plate jurisdiction for this industry; it is one of the world's densest concentrations of sterile fill-finish, biologics drug substance, API, and increasingly ATMP-adjacent manufacturing capability.

The Exposure: Roughly a third of Ireland's goods exports go to the United States. The tariff turbulence of 2025, including the Section 232 investigation into pharmaceutical imports, tariff threats that at one point reached triple-digit percentages in political rhetoric, and the eventual EU–US framework capping pharmaceutical tariffs at 15%, was a stress test of the Irish model. The lesson was that policy stability, both transatlantic and within the EU, is now the single most valuable commodity the sector can be given.

3. The Files on the Table

3.1 The General Pharmaceutical Legislation ("Pharma Package")

The first comprehensive revision since 2004 touches nearly everything: regulatory data protection (RDP) periods, EMA procedures and timelines, security of supply obligations, environmental risk assessment, the Bolar exemption, hospital exemption for advanced therapies, antimicrobial incentives, and electronic product information.

The central tension has been between access (getting medicines to all 27 member states faster and cheaper) and competitiveness (keeping Europe attractive for innovation investment). For a manufacturing and development economy like Ireland's, the evidence supports a landing zone that retains an internationally competitive baseline of regulatory data protection, simplifies committees, and implements environmental rules without stranding compliant capacity.

3.2 The Critical Medicines Act

Proposed in March 2025 to address shortage crises, this Act includes strategic-project designation for manufacturing investments in critical medicines, procurement reform to weigh supply security alongside price, coordinated stockpiling, and support for supply-chain diversification.

Instrument	Objective	Stakes for Ireland
Strategic Projects	Support investments in critical active ingredient manufacturing within the EU.	Opportunities for Irish API sites to secure fast-track approvals and state aid.
Procurement Reform	Weigh supply security alongside price.	Favors high-standard, resilient manufacturers based in Ireland.
Shortage Auditing	Coordinated reporting of supply vulnerabilities.	Increased demand for specialized quality and logistics professionals.

3.3 The Biotech Act

Expected before end-2026, the Biotech Act aims to consolidate fragmented regulation, accelerate lab-to-fab translation, and stem the flow of European biotech IP scaling in Boston rather than in Europe. The Irish Presidency will likely chair the first Council discussions of the proposal, helping frame it as an innovation priority.

3.4 The MFF, FP10, and Health Research Funding

The post-2027 Multiannual Financial Framework negotiation will determine funding for the successor to Horizon Europe, EU4Health, and HERA. A Presidency that keeps life-sciences R&D visibly on the table performs a service to every research hospital, university spin-out, and R&D site in Europe.

3.5 Implementation Files: HTA, EHDS, AI Act

Three already-adopted frameworks reach critical implementation phases: the HTA Regulation's joint clinical assessments (applying to oncology and ATMPs since January 2025), the European Health Data Space (EHDS, in force since March 2025), and the AI Act's rollout as it intersects with medicines development, pharmacovigilance, and manufacturing.

3.6 Transatlantic Stability

The 2025 framework agreement capping pharmaceutical tariffs at 15% converted an existential threat into a manageable cost, but its durability requires tending. Parallel tracks include deepening the EU–US Mutual Recognition Agreement on GMP inspections and defending global regulatory convergence through ICH.

Multilateral coordination of pharmaceutical regulatory policy remains key to long-term industrial predictability.

4. Impact Analysis: What This Means for Output and Investment

Consider two stylised scenarios for how the next 18 months of EU policy could break.

SCENARIO A: THE CONSTRUCTIVE LANDING

The pharma package concludes with competitive RDP and streamlined EMA procedures; the CMA passes with funded strategic-project machinery; the Biotech Act launches on a competitiveness framing; health research funding survives the MFF's first cut intact; and transatlantic tariff arrangements hold.

Outcome: Parked capital projects green-light; biopharma capital expenditure in Ireland sustains its multi-billion-euro cadence; and regulatory and quality hiring accelerates.

SCENARIO B: THE STALLED LANDING

Trilogues stall past 2026; uncompetitive RDP baselines are adopted; the CMA remains unfunded; and FP10 takes a deep cut.

Outcome: Capital investment incrementally tilts toward US and Asian sites, showing up in Irish data only years later as expansions that never happened, the invisible graveyard of industrial policy failure.

The gap between these scenarios is not rhetorical. For a sector exporting on the order of €100 billion annually from Ireland, even single-digit percentage differences in long-run investment trajectory represent billions in output and thousands of career opportunities. The Irish Presidency cannot guarantee Scenario A, as no presidency can, but it is among the few actors on earth with real influence over which path Europe takes, in exactly the window when the paths diverge.

5. Recommendations

5.1 For the Presidency (as honest broker)

- Prioritise conclusion of the pharma package trilogues within the term, spending political capital on the genuinely contested incentive provisions.
- Land the Critical Medicines Act with its funding and procurement provisions intact, championing supply security in procurement.
- Give the Biotech Act a competitiveness-first Council framing at its first presentation.
- Defend health research in the MFF negotiation's formative phase (FP10, EU4Health, HERA).
- Drive implementation coherence across HTA joint assessments, EHDS, and AI Act guidance.
- Sustain transatlantic regulatory and trade stability, including advancing MRA scope discussions.
- Put life-science skills on the European agenda, linking the Union of Skills to bioprocessing and regulatory needs.

5.2 For Ireland nationally (in parallel, outside the chair)

- Publish and fund the National Life Sciences Strategy to synchronize domestic and EU timelines.
- Deliver the physical enablers: grid capacity, water, and planning certainty for manufacturing.
- Maintain fiscal competitiveness for innovation, building on R&D tax credit enhancements.
- Resource the HPRA to expand its EU-level scientific leadership and rapporteurships.
- Double down on talent infrastructure: NIBRT's model, apprenticeships, and Springboard+ conversion courses.

5.3 For professionals

- **Regulatory Science:** Focus on HTA joint assessments, EHDS, and e-PI implementation.
- **Quality & Supply Chain:** Target CMA security-of-supply compliance and dual-sourcing audits.
- **Digital & Data:** Develop capabilities in CTIS fluency, EHDS data governance, and AI-in-GxP validation.
- **Bioprocessing & ATMP:** Acquire bioprocessing and advanced therapy skills, which remain in short supply.

6. Conclusion

Presidencies are judged in retrospect by what they closed, not what they chaired. Ireland's 2013 term is remembered because it delivered. The 2026 term arrives with a heavier and more consequential life-sciences docket than any presidency in EU history, and it arrives to a member state whose economy, workforce, and policy establishment understand this industry from the cleanroom floor up.

The expectations are high because the opportunity is real. A balanced pharmaceutical package, a funded Critical Medicines Act, a well-launched Biotech Act, protected research budgets, and transatlantic calm would together mark the strongest six months of European pharmaceutical policy in a generation—for patients first, and for the industry and professionals who serve them, everywhere from Ringaskiddy to Rzeszów.

Ireland did not choose this timing. But it is difficult to imagine a presidency better matched to the moment.

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About the Author

Sreepriya Prasannan is the Founder and Lead Editor of Priya Life Science. With a deep passion for the Irish pharmaceutical and MedTech sectors, she specializes in sharing actionable career insights, digital regulatory trends, and GMP compliance strategies.