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Building Sustainable Health Innovation Policies Across Europe: The I3HIES RHIES Policy Mix Report

(Article)

The I3HIES consortium has released a comprehensive **RHIES Policy Improvement Report**, capturing the progress of five European regions as they reform their health innovation ecosystems. The report demonstrates how regional and national actors can turn short-term projects into long-term structural change — ensuring that innovation not only happens, but lasts.

Covering **Slovakia, Poland, Romania, Slovenia, Lithuania and Hungary**, the report summarises concrete policy actions developed between late 2024 and mid-2025. Each partner used the **RHIES methodology** to identify bottlenecks, engage policymakers, and design actionable improvements within existing governance frameworks such as Recovery and Resilience Plans (RRPs), Smart Specialisation Strategies (S4), and national government programmes.

From pilots to permanent systems

In **Slovakia**, the partner Gravity o.z. tackled the challenge of sustaining community-based healthcare after RRP funding ends in 2026. Their proposed **Sustainable Community Health Funding Mechanism** transforms pilot Community Integrated Care Centres into a permanent, reimbursable component of the national health-insurance system. By linking payments to preventive outcomes and chronic-care continuity, Slovakia's reform sets the stage for long-term financial sustainability in community health.

In **Poland's Pomorskie region**, authorities revised the **Quality Programme 2030**—a flagship regional health-policy document first adopted in 2017. Supported by Interizon Cluster, the new edition focuses on digital drug management, internal quality systems, and patient-access improvements through e-health platforms. Hospitals across the region now work together in expert teams and audits, establishing Pomorskie as a leader in data-driven quality governance.

In **Hungary**, MediKlaszter participated in the **development of the Health Priority section of the National Intelligent Specialisation Strategy (NISS)** — at a time when the medical technology/health industry had become a designated key industrial strategic sector.

MediKlaszter, as a professional organisation representing the **medical technology industry**, also participated in the **preparation of the Strategy for strengthening Hungarian micro, small and medium-sized Enterprises (2019–2030)** and provided **expert support** for the **preparation of the Section 4.2 – Health Industry of Hungary's Competitiveness Strategy (2024–2030)** as well.



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Regulation, co-creation and policy anchoring

In Hungary, **MediKlaszter** elaborated a **complex package of measures executable on two levels (EU and Member State)**, capable of **providing solutions for the preparation of domestic MedTech enterprises (SMEs) for MDR compliance** through financial instruments, the creation of an enforceable regulatory environment, clinical trials, targeted sectoral research, development and innovation support, and simultaneously through governance development. At the same time, it mitigates the immediate burdens of eIFU and cybersecurity obligations and ensures the continuity of patient care.

By combining targeted financing, coordinated governance, and innovation-friendly adaptation, the initiative ensures that regulatory modernization does not come at the expense of competitiveness or patient safety.

Through these measures, **Hungary positions itself as a regional model in the MDR transition**, supporting both economic resilience and the sustainability of healthcare provision.

Romania's **Cluj IT Cluster** addressed a national regulatory barrier: the absence of domestic MDR/IVDR certification capacity for medical devices. Through I3HIES, they developed a proposal under the **National Recovery and Resilience Plan (NRRP)** to establish accredited national notified-body infrastructure by 2026. This change will cut certification costs by up to 50 percent and enable Romanian med-tech SMEs to compete effectively on the EU market.

In **Slovenia**, **Technology Park Ljubljana** focused on bridging innovation policy with healthcare practice. Their policy improvement embeds **co-creation**—joint pilot testing and living labs between SMEs and hospitals—as an eligible activity in the Operational Programme for EU Cohesion Policy 2021–2027. A new interinstitutional working group, including the Ministry of Health and national innovation agencies, now ensures alignment between funding calls and healthcare needs. Additionally, Slovenia is expanding digital-health training for educators and students, strengthening long-term adoption capacity.

Finally, in **Lithuania**, the **Lithuanian Innovation Centre** achieved a national milestone by integrating biomedical innovation into the **Government Programme** approved in December 2024. This embeds innovation as a strategic government priority, with the Ministries of Health and Economy preparing a five-year roadmap for clinical-trial capacity, research collaboration, and technology transfer. Lithuania's case exemplifies policy anchoring at the highest political level.

A coherent European policy mix

Together, these nine improvements form a connected European policy mix that spans the full innovation-to-adoption cycle:

- **Regulatory capacity (Romania)** enables companies to bring products to market;
- **Co-creation (Slovenia) and quality systems (Poland)** ensure technologies work in real clinical environments;
- **Financing reform (Slovakia)** sustains them;



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- National anchoring (Hungary, Lithuania) embeds them in long-term governance.

The report concludes that while contexts differ, the partners' actions share a common foundation: evidence-based analysis, participatory policymaking, and cross-sector collaboration. Each reform transforms an isolated pilot or regional initiative into a sustainable element of the broader European Health Innovation Ecosystem.

Policy learning in practice

The RHIES Policy Improvement Report is more than documentation — it is a roadmap for replication. It shows that meaningful policy change can occur even within existing instruments, provided there is structured methodology, stakeholder commitment, and a focus on measurable outcomes. By 2025, all five regions had advanced from planning to implementation, turning strategy into practice and practice into policy.

The full report, *“Policy Mix Development – RHIES Policy Improvement Report,”* is available through the I3HIES consortium.

