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Technological sovereignty in healthcare innovation and production for defence: proposal for an evaluation index to guide European policies

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ABSTRACT

This paper investigates the strategic importance of sovereignty in health innovation for defence within the European Union, addressing vulnerabilities exposed by recent pandemics and geopolitical tensions. It traces the evolution of technological sovereignty and emphasises the imperative for autonomous capabilities in military-medical technologies amid global shifts, including China's industrial policies and U.S. protectionism. The study proposes a technological sovereignty index (TSI) for evaluating sovereignty across multiple dimensions: research intensity, patent ownership, domestic production and supply chain resilience. The TSI provides decision-makers with actionable intelligence to identify capability gaps and guide targeted investments. Embedding technological sovereignty in EU health innovation governance strengthens strategic autonomy and security, establishing a structural pillar of European resilience in an increasingly contested geopolitical environment.

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Introduction

Technological sovereignty and strategic autonomy have become central to health innovation for defence, where technological mastery directly underpins operational readiness and military resilience. For the European Union, securing independent capabilities in defence health innovation addresses vulnerabilities exposed by COVID-19 and intensifies great power competition (Council Conclusions on Enhancing Preparedness et al., 2021). The return to high-intensity warfare on European soil since 2022 has challenged Europe's capacity to build substantial defence capabilities across critical areas, including defence health innovation, cyber security and emerging technologies (Anghel & Jones, 2023). In this context, sovereignty refers to the EU's ability to research, develop, produce and deploy critical medical technologies essential to both public health crises and military operations. This ambition echoes Bodin's classic definition of sovereignty as the 'absolute and perpetual power of a republic' (Bodin, 1576), refined by Le Fur to emphasise exclusive authority within a broader legal order (Le Fur, 1896). The concept has evolved to encompass control over the technological and industrial foundations necessary for military-medical autonomy (Luzeaux, 2022). Technological sovereignty in the European context denotes the EU's ability to reduce external dependencies in critical health and defence technologies whilst retaining the power to shape industrial, ethical and regulatory frameworks reflecting European values (Laïdi, 2024). This forms part of broader economic sovereignty, rooted in the link between technological leadership and industrial capacity to transform innovation into operational capabilities (Jelili, 2023).

The industrial dimension—the ability to develop, manufacture and sustain defence-relevant health innovations within Europe—lies at this ambition's core. Sovereignty is hollow if Europe remains dependent on non-EU supply chains for vaccines, diagnostics, or biomedical defence materials. As Poirier defines it (Poirier, 2010), strategic autonomy is the freedom to choose one's path free from external coercion. In the EU, this translates into a collective ability to pursue shared health-security industrial

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policy, where member states align investment strategies and regulatory frameworks (Clerc & Baillon, 2020). The European Defence Industrial and Technological Base (EDITB) represents efforts to harmonise cooperation, innovation and competitiveness amongst member states' national defence industries to enhance strategic autonomy. Amongst European countries, 'interoperability' has emerged as a solution enabling systems, units, or organisations to operate together through compatible doctrines, procedures and equipment (Beaudouin, 2019), benefiting widely the US defence industrial base (Wencker, 2023). More recently, 'expanded military cooperation' takes form through Multinational Joint Armament Programmes (FCAS, MGCS) and PESCO projects, permitting cost-sharing and clear European sovereignty for complex technologies (Droff & Malizard, 2023). If armament is one of the first sectors that can in mind when we talk about state sovereignty, pharmaceuticals and health are also highly critical in the same way as the fields of communication systems and food. This observation is shared on both sides of the Atlantic and undoubtedly beyond (Hérault, 2021). The creation of value chains in a context of increased international competition pits the sovereignty of different powers against each other in the race to attract and control value chains in the field.

As Kwet (2019) demonstrated, technological sovereignty determines not only economic resilience but also a state's ability to project power and preserve strategic influence in contested global orders. 'Resilience'—the ability to face challenges in terms of recovery, adaptability and sustainability—plays an essential role in sovereignty growth. Kelsen asserts that sovereignty, as supreme authority, is a characteristic of legal order, making state sovereignty inherently tied to national legal systems' relationships with international law (Kelsen, 1960). The return of hard power in international affairs positions the EU as a crucial framework for exercising 'pooled sovereignty' (Habermas, 2012). However, the German Federal Constitutional Court reaffirmed that European sovereignty remains a political aspiration, as military force and defence planning remain exclusive national competences (Federal Constitutional Court of Germany: Judgement of the Second Senate, 2009). Nonetheless, the Versailles Declaration in 2022 highlights the growing political agreement around European sovereignty, converging on 'bolstering our defence capabilities' and 'a more robust economic basis', which is reinforced by emerging disruptive technologies, including biodefence platforms, precision medicine and AI-enabled diagnostics. As Clerc and Cappe de Baillon (2020) argue, technological sovereignty is inseparable from industrial sovereignty, particularly where innovation underpins strategic power.

The geopolitical imperative for technological sovereignty

The return of power politics has strengthened imperatives for industrial and technological sovereignty, particularly in healthcare innovation for defence. Since 1991, free trade and globalisation have fostered economic integration and interdependence between economies, markets, societies and cultures worldwide (Scholte, 2008). Liberal thinkers like Slaughter defended globalisation's pacifying virtue, favouring decentralised networks generating diplomatic opportunities (Slaughter, 1997). However, interdependence creates new risks and exploitation tools. The United States gradually acquired control over financial (SWIFT) and digital (Internet) networks, using them to increase coercive power and reinforce economic-geopolitical dominance (Farrell & Newman, 2019). Technological sovereignty concepts link to American and Chinese tech giants' rises. China initially viewed American digital power as threatening its economic-political system, promoting 'cyber sovereignty' or 'Internet sovereignty' whilst building technology champions supported by research ecosystems geared towards economic domination (Lehuedé, 2024). This paradigm shifted with Brexit and Trump's 2016 election, signalling rejection of globalisation's excesses. Trump's America First agenda, critiquing free trade as driving deindustrialisation, translated into a trade war targeting China and the EU (Velut, 2023). Technology has proven central, with Huawei's 5G exclusion framed as a national security imperative (Salamatian, 2020). By 2019, US tariffs rose from 3.1% to 21.2%, illustrating shifts towards economic nationalism mirroring European concerns regarding forced technology transfers. China's technological rise in digital infrastructure, batteries and clean technologies has further exacerbated trends (Lanckriet & Ruet, 2019). Since the early 2000s, China has combined state capitalism, strategic acquisitions and protectionist policies, consolidating dominance in key sectors. The Made in China 2025 plan explicitly aims to 'deploy the socialist system's ability to concentrate forces to accomplish major projects', supporting national champions through subsidies and

preferential financing, often breaching WTO rules. Success is visible in electric vehicles, where Chinese firms threaten Europe's automotive industry, representing 10% of European manufacturing output. The EU experienced Chinese industrial strategies directly, particularly in solar panels, where protective measures imposed in 2013 were quickly withdrawn facing Chinese retaliatory tariffs (Finon, 2025). China First Secretary Xi Jinping's 2018 declaration that technological self-sufficiency was essential given rising protectionism amplified concerns. Biden's Inflation Reduction Act, whilst framed as climate policy, is widely seen as attempting to capture clean technology supply chains, relocating high-value production to American soil at European expense (Draghi, 2024).

The EU's shift towards assertive industrial policy began in 2016–2017, when the 'Kuka case', the Chinese acquisition of Germany's leading robotics firm – triggered reassessment of open investment policies in sensitive technologies (Mertens-Lafay, 2020). This shift, driven by Germany's industrial anxieties, aligned with France's longstanding advocacy for European industrial policy, providing a political foundation for a proactive EU industrial strategy. Draghi (2024) report on European competitiveness acknowledged Europe's past over-reliance on global value chains and failure to anticipate geopolitical weaponisation of supply chains (Draghi, 2024). Both China and the US use industrial policy to undermine Europe's technological-industrial position. China vertically integrates entire green technology supply chains, creating structural overcapacity undercutting European producers, whilst the US combines industrial policy tools, protectionism and geopolitical leverage to attract foreign investment and reorient global supply chains to its benefit (Di Carlo & Schmitz, 2023). In this context, EU pursuit of technological sovereignty in healthcare innovation for defence becomes essential to broader industrial strategy (Regulation (EU) 2019/452 of the European Parliament & of the Council of 19 March 2019 Establishing a Framework for the Screening of Foreign Direct Investments into the Union, 2021; Velliet, 2022).

Governance and actors in European health innovation sovereignty

Achieving technological sovereignty in health innovation for defence requires coordinated interplay between public authorities, private industry (including EDITB), research institutions and specialised agencies (Csernatoni, 2022). The European Commission's role has expanded significantly since the Kuka case, introducing investment screening, foreign subsidy controls, public procurement reciprocity requirements and anti-coercion instruments (Di Carlo & Schmitz, 2023; European Commission: Secretariat-General et al., 2023; Regulation (EU) 2022/1031 of the European Parliament et al., 2022). This evolving de-risking doctrine combines market oversight with defensive measures to protect strategic health sectors. Sectoral legislation, including the Net-Zero Industry Act, Chips Act, Critical Raw Materials Act and Critical Medicines Act reinforce sovereign industrial capabilities. European funding instruments, including Horizon Europe and the European Defence Fund, increasingly prioritise dual-use health innovations, underscoring strategic overlap between public health resilience and military readiness.

Member states retain crucial competencies in research funding and defence planning. Since COVID-19, national recovery plans and greater flexibility in state aid rules, particularly through Important Projects of Common European Interest (IPCEI), have enabled direct support for strategic health innovations (Levratto, 2024). The European Health Emergency Preparedness and Response Authority (HERA) and the European Defence Agency (EDA) form an institutional backbone linking health security with defence preparedness. HERA focuses on anticipation, preparedness and civilian stockpiling, whilst EDA supports medical capabilities development for military forces. The European Medicines Agency (EMA) reinforces regulatory sovereignty through independent certification processes, whilst the European Centre for Disease Prevention and Control (ECDC) provides epidemiological intelligence essential for both public health planning and military health risk assessments (Calderaro & Blumfelde, 2022). However, some marketing authorisations for medical countermeasures qualified nationally before EMA's creation are not systematically extended to all member states. Systematic cooperation between HERA, EDA, EMA, ECDC and relevant Directorate Generals (SANTE, DEFIS and GROW) is essential for aligning threat intelligence, foresight capabilities, regulatory strategies and industrial planning (Nepelski & Van Roy, 2021). Implementation of a steering committee, including the EU and national dedicated bodies providing strategic direction and visibility, could enhance EU sovereignty.

The private sector plays complementary roles. Large companies ensure production capacity for strategic vaccines, diagnostics and biodefence technologies is located within Europe, whilst small and medium enterprises develop specialised operational medicine tools. In Europe, public bodies drive research and innovation development, whilst private sector involvement signals innovation maturity and expected profitability. The European Commission acknowledges that for truly strategic technologies, conventional market forces are insufficient; public intervention is necessary to steer innovation toward collective strategic goals (Seidl & Schmitz, 2024). This shift echoes List's argument for temporary protection and structured support to develop domestic industrial capacities when competing with technologically advanced rivals (List, 1909). As Mazzucato highlights, the state plays critical roles as an entrepreneurial actor, de-risking early-stage innovations and aligning technological trajectories with public interest objectives (Mazzucato, 2013). In health innovation for defence, this means aligning public R&D funding, targeted procurement and regulatory processes with strategic autonomy goals, ensuring that innovation ecosystems evolve into sustainable competitive advantages (Edquist & Borrás, 2013). This context of increasing global competition raises the absolute need for the EU to develop and coordinate health innovation policies in defence, protecting and strengthening technological sovereignty (Soete & Burgelman, 2023).

Methodology: how to assess the sovereignty of a technology?

Maturity indices in healthcare innovation: essential for development tracking but insufficient for sovereignty assessment

Before strengthening EU technological sovereignty in defence health innovations, it is essential to measure it. Applying sovereignty principles to a given technology requires analysing the entire value chain, from initial conception to market deployment. Technology readiness level (TRL), integration readiness level (IRL), manufacturing readiness level (MRL) and societal readiness level (SRL) provide widely used tools for evaluating maturity, integration capacity, production readiness and societal acceptance of healthcare innovations (see Table 1) (Hook-Barnard et al., 2013; Palluault & Omer, 2022). TRLs, which were originally developed by NASA, assess progress from basic research (TRL 1) to full operational deployment (TRL 9), tracking scientific validation, preclinical testing, clinical trials and regulatory approval. IRLs evaluate how effectively technologies integrate into existing systems (IRL 1–9), ensuring that devices interface seamlessly with hospital information systems and medical equipment. MRLs assess whether technologies can be produced at scale whilst maintaining quality and supply chain reliability (MRL 1–10), ensuring the transition from laboratory synthesis to industrial manufacturing compliant with good manufacturing practices. SRLs measure society's readiness to adopt innovations (SRL 1–9), addressing public trust, cultural acceptance and alignment with existing practices (Palluault & Omer, 2022). In healthcare, SRLs evaluate whether patients, professionals and institutions are prepared to accept and utilise new solutions; particularly pertinent for vaccines, where biological efficacy may be undermined by hesitancy or institutional distrust.

Despite their utility for tracking innovation development, these indices reveal significant limitations when applied to sovereignty assessment. Whilst they effectively measure technical maturity, integration capability, manufacturing readiness and societal acceptance, they systematically overlook critical geopolitical, economic and strategic factors essential to strategic autonomy. A technology achieving high scores across all four indices may still depend entirely on foreign patents, outsourced production, imported critical components, or non-EU data infrastructures, leaving Europe vulnerable during geopolitical tensions or supply chain disruptions. A medical countermeasure may be clinically validated, well-integrated into health systems, manufactured at the industrial scale and widely accepted by professionals and populations, yet remain strategically dependent if active ingredients are sourced exclusively from non-EU suppliers, production facilities are located outside Europe, intellectual property is controlled by non-European entities, or emergency regulatory approval depends on non-EU authorities. This disconnect highlights the fundamental need for a complementary evaluation framework tailored specifically to technological sovereignty in health innovation for defence. Such a framework must extend beyond maturity and acceptance levels, incorporating indicators of patent ownership, domestic production capacity, supply chain resilience, regulatory autonomy and strategic stockpiling capabilities. By integrating these strategic dimensions, Europe could assess whether key health technologies are not only

Table 1. Synopsis of maturity indices applied to healthcare innovation. TRL, IRL and MRL assess technical, integration and manufacturing maturity respectively, whilst SRL evaluates societal readiness for adoption. Together, these indices provide comprehensive assessment of innovation development and acceptance. However, high scores across all four dimensions do not guarantee technological sovereignty, as they do not capture geopolitical dependencies, patent ownership, production localisation, or supply chain resilience—the essential prerequisites for strategic autonomy in defence health innovation.

Index	What it measures	Key question for stakeholders	Progression stages	Healthcare application examples
TRL (technology readiness level)	Evaluates the scientific validity and technical viability of an innovation	Does the technology demonstrate robust scientific and engineering principles, progressing towards operational deployment?	TRL 1: basic scientific research begins TRL 2: formulation of technology concept TRL 3: experimental proof-of-concept TRL 4–5: validation in laboratory and simulated environments TRL 6–7: prototype demonstration in relevant and operational environments TRL 8–9: final validation and full commercial deployment	AI-based diagnostic tools moving from algorithm training (TRL 3) to clinical trials (TRL 6–7), then to certified decision support systems in hospitals (TRL 9)
IRL (integration readiness level)	Assesses the degree to which a solution can interoperate with existing technical, logistical and institutional systems	Can the innovation be seamlessly integrated with current infrastructures and workflows?	IRL 1: awareness of integration need IRL 3: early proof of integration concept IRL 5: intermediate integration trials with stakeholders IRL 7: validated end-to-end integration IRL 9: routine, stable operations within broader systems	Real-time biosurveillance tools integrating with national health registries and cross-border alert systems; immunisation data syncing with EHRs in hospital networks
MRL (manufacturing readiness level)	Measures readiness for scalable, compliant and cost-effective manufacturing	Is the innovation reproducible at scale under regulatory and quality-controlled conditions?	MRL 1: conceptual identification of production needs MRL 3: assessment of manufacturability and regulatory landscape MRL 5: pilot-scale manufacturing with quality testing MRL 7: full-scale validated production line MRL 10: commercial-scale, optimised production with supply chain stability	Rapid production of mRNA vaccines through modular biomanufacturing platforms; automation of device assembly lines using Industry 4.0 techniques
SRL (societal readiness level)	Gauges societal, ethical and user preparedness to adopt the innovation	Is the innovation acceptable, trusted and usable by end-users and stakeholders in real-world contexts?	SRL 1: identification of a societal need SRL 3: engagement with civil society and key user groups SRL 5: early field deployment with behavioural studies SRL 7: cultural and ethical acceptability established SRL 9: broad, equitable adoption with social impact monitoring	COVID-19 vaccine rollout involving public trust campaigns, misinformation management, equitable access mechanisms and feedback-informed updates to distribution policies

technically mature, well-integrated, industrially scalable and socially accepted, but also geopolitically secure and industrially autonomous—the essential prerequisites for genuine sovereignty in defence health innovation.

Objectives and implementation of a healthcare technology sovereignty index (TSI)

Assessing technological sovereignty in health innovation for defence, particularly in medical counter-measures (MCM) against CBRN threats, requires a multi-dimensional approach for evaluating scientific

output, patent activity, investment levels and human capital. The construction of a technological sovereignty index (TSI) would rely on data from European institutions, national agencies and international bodies, combined with relevant quantitative and qualitative indicators. However, methodological obstacles must be overcome. Data access represents a major challenge, as sensitive defence-oriented health technologies information is often classified or unevenly disclosed across the EU. Harmonising national data collection methodologies is critical to ensure consistent pan-European comparisons, whilst rapid technological evolution requires regular updates to maintain the index's relevance. Defence and health data standardisation amongst Europe is unavoidable if coherent common policy is to be pursued despite national sensibilities. Implementing a health technological sovereignty strategy faces structural and political challenges. National initiatives fragmentation complicates European coordinated policies where defence and public health overlap. Moreover, intensified global competition—particularly from China and the United States—heightens the need for stronger intellectual property protection and more effective screening of foreign investment in strategic sectors. Nevertheless, the expansion of public–private partnerships, combined with assertive European innovation policies under Horizon Europe, the European Defence Fund and the Critical Medicines Act, offers favourable conditions for collaborative health innovation for defence. As Soete and Burgelman defined, balancing open science principles with technological sovereignty imperatives is one of Europe's central challenges where health security and strategic defence converge (Soete & Burgelman, 2023). If successfully adopted, a TSI would carry significant policy implications. By offering objective data on technological dependencies, industrial gaps and innovation leadership, it would guide public investment decisions in R&D and strategic industrial policy, whilst highlighting vulnerable segments, allowing policymakers to prioritise targeted investments and stimulate closer Member States cooperation. Technological sovereignty in healthcare for defence requires the consolidation of industrial capabilities, the protection of key technologies and the deployment of secure digital infrastructures across the health-security continuum. Establishing a European Healthcare Technology Sovereignty Index would offer both a practical tool for progress measurement and a strategic instrument to consolidate the EDITB in health defence across scientific, industrial and defence dimensions.

Current indices and the foundations for a healthcare TSI

Existing tools, such as the European Innovation Scoreboard, provide valuable comparative assessments of EU Member States' research and innovation performance. However, these instruments focus primarily on innovation performance rather than sovereignty, particularly in strategic sectors like health innovation for defence. The European Patent Office (EPO) supports technological sovereignty by streamlining patent processes and ensuring that European innovators secure intellectual property rights efficiently. The coordination of national and regional patent policies, combined with tax incentives and direct funding mechanisms, promotes patent filings in strategic health sectors. Horizon Europe funds the translation of research into patented technologies, reinforcing Europe's capacity to commercialise biomedical innovations within EU jurisdiction. Protecting these innovations requires a comprehensive IP strategy that combines trade secret laws, regulatory safeguards and foreign investment screening. The unitary patent system streamlines cross-border patent protections, but securing European sovereignty also requires the protection of European start-ups from non-EU acquisitions, particularly in the pharmaceutical, biotech and defence sectors. As the Draghi report suggests, Europe's technology start-ups suffer from the lack of a unified capital market to grow and compete with Asian and American rivals (Draghi, 2024). The COVID-19 pandemic underscored the importance of local manufacturing capacity, highlighting vulnerabilities from import dependencies on active ingredients and critical medical components (Bodo & de Filippi, 2025). Tracking the domestic production share of essential pharmaceuticals and biotechnologies would provide critical input for a sovereignty index alongside public R&D funding and venture capital investment indicators. Supply chain resilience must feature prominently, measuring Europe's dependency on non-EU suppliers for strategic raw materials, disruption frequency, supply chain alternatives and local manufacturing mobilisation speed. HERA's contribution to strengthening Europe's countermeasure production capabilities should be explicitly tracked.

TSI construction faces challenges from information technology's growing importance in healthcare device development. Digital component integration in tests or telemedicine services, particularly those based on artificial intelligence, makes dependency assessment complex. Distinguishing different layers of the digital value chain is needed to measure dependence on foreign solutions (Heeks & Spiesberger, 2024), including natural resources (rare earths), electronic components, communication networks, dataspaces, intelligence functions, applications and access terminals. A robust TSI must assess regulatory and financial incentives supporting domestic innovation, ensuring that European firms remain competitive in advanced health technologies. Technology transfer agreements within Europe would reflect the extent to which European-developed technologies remain under European control. Europe's ability to influence international standards for digital health, biomedicine and artificial intelligence directly impacts its regulatory sovereignty; the active participation of European experts in standardisation committees should be closely monitored and coordinated. An effective sovereignty index would track expertise development in biotechnology, health-related AI and biomedical engineering, ensuring that Europe maintains the necessary human capital for long-term innovation leadership. A comprehensive analytical framework must integrate indicators covering research intensity, patent activity, participation in research programmes and industrial independence. Inspiration could come from the Australian Strategic Policy Institute's Critical Technology Tracker (Wong Leung & Robin, 2025). Digital infrastructure resilience must be factored in, assessing cybersecurity measures, data localisation policies and the adoption of European cloud solutions not subject to extraterritorial legislation such as the U.S. Cloud Act (Calderaro & Blumfelde, 2022). The index should incorporate sensitive data protection standards, particularly GDPR implementation and enforcement, to assess how effectively Europe controls its health data—a key element of both technological and ethical sovereignty.

A framework for evaluating healthcare innovation sovereignty: proactive, defensive and prosperity-driven dimensions

This framework may be further operationalised by applying structured MCDA methodologies such as swing weighting, analytic hierarchy process (AHP), or discrete choice experiments. These techniques allow for the empirical derivation of criterion weights based on stakeholder preferences and trade-offs, thereby reducing subjectivity in score aggregation (Belton & Stewart, 2002). Moreover, the TSI's structure is compatible with a dynamic implementation model—capable of evolving as new data or threats emerge. Rather than serving as a static benchmark, the index could support real-time policy simulations under different geopolitical or technological scenarios. This feature has been advocated in recent MCDA-based resilience assessments in cyber and biosecurity (Linkov & Kott, 2025). Finally, the integration of both quantitative proxies (e.g. % of localised production, average certification delay) and expert-derived indicators (e.g. regulatory autonomy) ensures that the model remains transparent, traceable and adaptable. This mixed-methods foundation strengthens the policy relevance of the TSI while allowing for refinement as data ecosystems mature.

Building on Luzeaux's work on cloud sovereignty and Ben Jelili's on economic sovereignty, we then propose a structured framework to evaluate technological sovereignty in healthcare innovation, particularly for defence applications (Jelili, 2023; Luzeaux, 2022). This framework integrates three complementary dimensions – proactive, defensive and prosperity-driven sovereignty – reflecting the need for technological and strategic independence alongside citizen-centric health benefits in a globally competitive and geopolitically tense environment. The proactive dimension refers to long-term investments in building technological leadership through research infrastructure, patent protection and public–private partnerships, fostering Europe's ability to shape technological trajectories in biomedical engineering and health innovation for military resilience (Technological sovereignty in biomedical engineering: The focus on the human being, 2024). The defensive dimension addresses the preservation of strategic assets, ensuring that Europe retains control over critical technologies, health data flows and supply chains, which are increasingly framed as digital sovereignty in health data governance and AI-driven diagnostics (Mensah et al., 2024). The prosperity-driven dimension ensures that technological sovereignty enhances health security and equitable access to cutting-edge medical technologies, aligning strategic autonomy with broader public health objectives (Frenk et al., 2014). Together, these three dimensions guide policy choices to foster collaborative and sovereign innovation ecosystems where health

technologies contribute simultaneously to strategic autonomy, economic resilience and inclusive health security. This tripartite framework applies across the entire healthcare innovation lifecycle, from basic research to large-scale production and stockpiling. Each technology can be classified according to its sovereign control level using an adaptation of Luzeaux's taxonomy: (1) complete sovereignty: full control across all stages, from R&D to production and deployment; (2) partial sovereignty: control over critical stages (e.g. R&D and regulatory processes), with some reliance on external suppliers for non-strategic inputs (excipients, replaceable parts, parts with European-produced equivalents); (3) degraded sovereignty: sovereignty limited to essential defence applications, with dependence on non-EU technologies for supporting processes; and (4) Absent Sovereignty: full dependence on external technologies and supply chains. By integrating these dimensions and classification levels into a TSI for healthcare innovation, European decision-makers would gain a dynamic tool to assess vulnerabilities, prioritise investments and guide targeted interventions, reinforcing Europe's technological self-reliance in biomedical innovation and health security. This framework draws methodological support from multi-criteria decision analysis (MCDA), a widely recognised approach for evaluating complex decisions involving competing objectives and incomplete information. Recent systematic reviews highlight how MCDA enables the integration of mixed quantitative and qualitative data through structured stakeholder engagement, scoring matrices and transparent weighting procedures (Antioch et al., 2024; Cinelli et al., 2020). The TSI's multidimensional structure—spanning proactive, defensive and prosperity-driven axes—parallels MCDA models designed for resilience and policy planning in critical infrastructure and public health. MCDA has been extensively applied to similar domains, including pandemic resilience planning, supporting countermeasure prioritisation and composite policy instrument design (Antioch et al., 2024). Hybrid approaches such as the analytic hierarchy process (AHP) and MACBETH (measuring attractiveness by a categorical-based evaluation technique) are increasingly used to elicit quantitative weights from expert judgement whilst maintaining interpretability (Bana E Costa et al., 2012; Saaty, 2008). These methods can strengthen the TSI by quantifying trade-offs among sovereignty dimensions consistently and replicability. In future iterations, applying AHP-based pairwise comparisons among policy goals could yield empirically grounded weights, reducing subjectivity and increasing comparability. As Linkov and Kott suggest, fusing qualitative resilience metrics with quantitative engineering assessments is particularly suitable for systems operating in uncertain or contested domains such as defence health innovation (Linkov & Kott, 2025). The TSI's inclusion of mixed indicators thus mirrors best practices from MCDA applied in cybersecurity, environmental risk and biosecurity governance. The multidimensional structure of the TSI reflects the need to balance quantitative indicators (e.g. production capacities or IP ownership) with qualitative, normative concerns (e.g. regulatory autonomy or ethical acceptability). Linkov and colleagues highlight the importance of structuring decision models that can accommodate such heterogeneous data types—a key feature of the TSI (Linkov et al., 2020). The TSI builds on these MCDA principles by incorporating a scoring matrix integrating both data-driven indicators and expert-derived thresholds. Whilst sovereignty levels (complete, partial, degraded and absent) may appear categorical, they are anchored in methodology applied in similar MCDA-based public decision tools. Scenario-based workshops with European stakeholders served to calibrate these levels based on consensus, echoing the Delphi technique often used in MCDA. By grounding the TSI in this methodological tradition, the framework avoids arbitrariness and positions itself within the growing literature advocating structured, value-based assessments of innovation policy under uncertainty, aligning with evolving EU governance logic where technological sovereignty is increasingly framed as both industrial policy and systemic preparedness.

The TSI construction begins with identifying eight fundamental dimensions capturing the entire healthcare innovation lifecycle for defence: research, development, certification, production tools, raw materials, civilian storage, military storage and deployment capacity (Table 2). Each dimension is described through key indicators that combine quantitative elements—such as the European scientific publications share, patents filed in biomedical technologies, or raw material dependency percentage on non-EU sources—with qualitative markers, such as certification authorities' independence, storage systems' interoperability, or rapid deployment capacity. This structure reflects a deliberate methodological choice: sovereignty cannot be captured by a single indicator but emerges from the interplay between knowledge production, industrial capacity, regulatory autonomy and operational readiness. However, whilst the eight dimensions in Table 2 provide essential granularity, their direct application would yield an index too complex for policy use. A tool designed to guide investment and regulatory decisions must balance comprehensiveness with operability. Therefore, dimensions are consolidated into four broader

Table 2. Eight dimensions and key indicators of technological sovereignty in healthcare innovation. This table details the initial structure of the proposed index, spanning from research capacity to deployment readiness. Each dimension is paired with operational indicators (e.g. patents, stockpiles and response times) to capture sovereignty-relevant attributes beyond simple innovation metrics. These dimensions are later consolidated in Table 3 for weighting and scoring.

Dimension	Description	Key indicators	Quantification possibility (examples)
Research	Technological sovereignty begins with mastering fundamental and applied research in biotechnology, pharmaceuticals and AI applied to health and defence	Patents deposited Share of European scientific publications in global total Percentage of GDP allocated to health and defence R&D Number of patents filed in biomedical and technological fields	Number of patents filed per year; % of global patent share
Development	Transforming research into prototypes and functional solutions requires sufficient industrial and financial capacity	Number of companies and start-ups engaged in biomedical and technological development; Amount of public and private investments in biotechnology and defence; Level of dependence on foreign funding for the development phase.	Number of biotech/medtech firms; % private/public funding from EU sources
Certification	Autonomy in certification ensures independence in validating the safety and efficacy standards of innovations	Existence of independent national/EU certification and regulation agencies; Average certification time for new medical and biotechnological devices; Export capacity of certified products according to European standards.	Existence of European agencies with independent effective authorisation process; average days to approve a device; # of certified exports
Production tools	A robust technological sovereignty requires a competitive industrial capacity to mass-produce medical and technological solutions	Number of European manufacturing plants for vaccines, medicines and medical devices; Level of robotics and automation in production; Percentage of production chains in Europe compared to imports.	Number of EU-based plants; % production localised in EU; degree of automation, production scale in Europe. # of factories able to produce each MCM needed in crisis time.
Raw materials	Control over strategic inputs (active ingredients, electronic components, rare metals) is a key factor in sovereignty	Level of dependence on imports for critical raw materials; Capacity of European extraction and processing sectors; Existence of strategic stockpiles of raw materials.	% raw material import dependency; volume of domestic extraction; stockpile volume regarding estimated needs in case of crisis
Civilian storage	Storage is essential to ensure resilience in health crises and maintain continuity of healthcare services	Volume of stocks of medicines and medical devices in Europe; Number of sovereign logistic platforms for healthcare; Autonomy of storage infrastructure (capacity, shelf life).	Days of inventory on hand; # of sovereign logistics hubs; storage autonomy index
Military storage	Storage of medical countermeasures in case of biological, chemical, or nuclear attacks is a national and European security issue	Level of strategic military stockpiles in Europe; Resupply times in case of crisis; Cooperation between member states for military storage infrastructure.	Volume and coverage of strategic reserves; crisis resupply time; joint EU protocols
Deployment	The ability to respond quickly in the event of a health or military crisis is a key marker of sovereignty	Average time for deploying medical resources in case of emergency; Rapid mobilisation of strategic reserves (medicines, vaccines); Rapid export capacity to strategic allies.	Time to deploy assets; % resources mobilised within 48 h; export responsiveness score

axes in Table 3: (1) research & development (25%)—capturing Europe's ability to generate knowledge, secure intellectual property and translate research into innovation; (2) production & raw materials (30%)—measuring industrial capacity, supply chain localisation and control over critical inputs, representing the core of strategic vulnerability; (3) certification & storage (25%)—assessing regulatory autonomy and ability to maintain resilient civilian and military stockpiles and (4) deployment & responsiveness (20%)—evaluating capacity to mobilise innovations and resources rapidly during crises. The weighting coefficients assignment reflects a qualitative judgement of each axis's relative strategic importance. Production & raw materials receives the highest weight (30%), as manufacturing disruptions or critical input shortages constitute the most immediate sovereignty risks, as demonstrated during the COVID-19 pandemic. Research & Development and Certification & Storage are weighted equally at 25%, acknowledging that technological leadership and regulatory control are equally vital for long-term autonomy. Deployment & Responsiveness is weighted slightly lower (20%), since countermeasure mobilisation ability depends on the previous three pillars' strength, though rapid response remains decisive during crises. The scoring system in Table 3 ranges from 0 to 100, where 100 signifies full sovereignty—complete European control and independence—and 0 indicates total external dependence. Intermediate scores capture

Table 3. Aggregation of sovereignty dimensions into four weighted axes. This table synthesises the eight dimensions of Table 2 into four broader categories (R&D, production & raw materials, certification & storage, deployment & responsiveness). Each axis receives a weighting coefficient and a 0–100 scoring scale. Proposed weightings (25%, 30%, 25% and 20%) are based on stakeholder consultations and aligned with MCDA methods like swing weighting. Total equals 100%. Sensitivity analysis is advised to examine how these weights affect final scores. This aggregation introduces a first step toward quantifying sovereignty, providing a structure for the comprehensive model developed in Table 4. Technological sovereignty index – aggregation & interpretation.

Dimension	Weighting coefficient (%)	Scoring scale*	Interpretation
Research & development	25	0–100	Evaluates the ability to drive innovation through patents, R&D investments and participation in research programmes
Production & raw materials	30	0–100	Assesses the capacity to manufacture and secure raw materials for essential health and defence technologies
Certification & storage	25	0–100	Measures the efficiency of certification procedures, storage resilience and regulatory autonomy
Deployment & responsiveness	20	0–100	Examines the speed and effectiveness of deploying technological solutions in response to crises

*100 = full sovereignty and 0 = no control.

sovereignty and vulnerability gradations. This scale's analytical value lies not only in providing an overall index but also in making imbalances visible. For example, an EU countermeasure may score near 90 in Research & Development but only 40 in Production & and Raw Materials, signalling that strong innovation capacity is undermined by insufficient manufacturing sovereignty. Such discrepancies allow decision-makers to target investments and reforms toward the weakest links. Table 3 therefore plays a pivotal methodological role, not merely simplifying Table 2 but bridging descriptive indicators and an operational model. By aggregating diverse dimensions into four weighted axes with clear scoring criteria, it transforms a broad conceptual framework into a structure comparable across technologies, trackable over time and applicable to policy choices.

As an example, supply chain resilience is operationalised within the TSI through multiple sub-dimensions, particularly under the 'production & raw materials' axis. This includes quantitative indicators such as the localisation of critical manufacturing infrastructure, the diversity and origin of raw material suppliers and the existence of strategic stockpiles. For instance, the indicator 'raw material security & stockpiling' captures both dependency ratios and reserve levels, allowing for a concrete assessment of supply vulnerability across essential inputs. As these indicators are scored across a four-level sovereignty scale, they enable the structured evaluation of resilience factors, including redundancy, autonomy and substitution capacity. By integrating these metrics into the aggregated axis of 'production & raw materials' (weighted at 30% in the TSI), the framework ensures that supply chain robustness is not treated as a peripheral issue but as a central determinant of technological sovereignty. This methodological approach aligns with existing MCDA models in national preparedness and critical infrastructure protection, where the resilience of upstream supply networks is a core criterion for assessing strategic readiness (Linkov et al., 2020; Linkov & Kott, 2025).

Thus, Table 3 ensures that the TSI is not just descriptive indicator mapping but the backbone of a practical composite index, setting the stage for full operationalisation of sovereignty measurement in Table 4, where each sub-dimension is defined with explicit thresholds for 'complete', 'partial', 'degraded' or 'absent' sovereignty.

TSI in detail: from general conception to precise indicator

To operationalise the TSI model, each sovereignty dimension has been disaggregated into measurable sub-dimensions with corresponding indicators (Table 4). These indicators employ a four-level scoring system—complete, partial, degraded or absent sovereignty—mirroring established approaches in cyber-resilience and biosecurity where data fragmentation necessitates integrating expert judgement with empirical thresholds (Linkov et al., 2020). Each sub-dimension maps to one of the four aggregated axes from Table 3, ensuring methodological continuity and weighting consistency. This multi-layered structure enables thematic depth whilst maintaining cross-domain comparability. Table 5 provides a simplified screening tool for rapid sovereignty gap diagnosis in time-constrained contexts, following best practices in

Table 4. Full technological sovereignty index (TSI) model for healthcare innovation in defence. This detailed framework assigns weights, indicators and scoring criteria for each sovereignty dimension. It operationalises the TSI by specifying thresholds for 'complete, partial, degraded and absent sovereignty'. This table constitutes the methodological core of the paper, translating conceptual dimensions into a measurable tool that can be applied to concrete medical countermeasures (e.g. vaccines, diagnostics and protective equipment).

				EU sovereignty			
Dimension	Sub-dimension	Weight (%)	Indicator	Complete	Partial	Degraded	Absent
Research & development (25%)	Research output	6%	Share of EU publications on research, development and production	>40% EU publications	25%–40% EU publications,	5%–25% EU publications	<5% EU publications, no EU patents or centres
			Number of specialised research centres	5+ specialised EU research centres	<5 Specialised EU research centres	No specialised centres but specialised labs	No specialist across Europe
	Technology transfer agreements	4%	Formal transfer agreements with EU industry	Agreements with multiple EU firms	Limited agreements with select EU firms	Mostly non-EU partners	No agreements
	R&D funding structure	6%	Public, private, hybrid EU-based funding with anti-relocation clauses	100% EU public and hybrid funding Anti-relocation clauses	Hybrid funding (50%–80% EU), Some external transfer allowed with an European authorisation	Hybrid funding (<50% EU), foreign dominant Some external transfer allowed with an National authorisation	Fully dependent on foreign funds No control on external transfer
	Training systems	4%	Specialised training on CRBN medical countermeasures	Mandatory training in core curriculum, reviewed every 2 years	Optional specialisation, reviewed every 5 years	Training available but not systematic	No training
	Research quality assessment	3%	Independent evaluation cycles	Every 2 years or less	Every 5 years	Every 10 years	No evaluations
	Technological watch & horizon scanning	2%	Active EU monitoring of disruptive innovations in the field	Horizon scanning mechanism operational across EU agencies	Partial scanning process at national level	Fragmented scanning with ad hoc initiatives	No systematic monitoring process
Industrial property, production & raw materials (30%)	Patent landscape	6%	Share of non-EU patents & EU patent control	<10% non-EU patents	10%–25% non-EU patents	25%–40% non-EU patents	>40% non-EU patents
	Patent environment	4%	Litigation frequency & patent citation impact	<2 litigations/year, Highly cited	2–5 litigations/year, Moderately cited	5–20 litigations/year, Limited citation	>20 litigations/year, Rarely cited
	Licensing practices	5%	Global & EU licensing activity	>20 global, >14 EU licences	5–20 global, 5–14 EU licences	1–5 licences	No licences
	Workforce & social resilience	5%	Adaptability & social stability as defined by European Labour Authority	Highly adaptable workforce & stable socio-political environment	Moderate adaptability & social stability	Low adaptability & rising social tensions	Inflexible workforce & high social instability
	Localisation & control of critical manufacturing	5%	Share of EU-based supply chains & production tools	100% EU-based	50%–100% EU-based	<50% EU-based	Fully dependent on non-EU
	Raw material security & stockpiling	5%	Source diversity, dependency & strategic reserves	>3 independent suppliers <15% non-EU dependency	3 independent suppliers 15%–40% non-EU dependency	<3 independent suppliers 40%–60% non-EU dependency	No independent supplier >60% non-EU dependency

(*Continued*)

Table 4. (*Continued*)

Dimension	Sub-dimension	Weight (%)	Indicator	EU sovereignty			
				Complete	Partial	Degraded	Absent
				6+ production weeks stock	4–6 production weeks stock	2–4 production weeks stock	<2 production weeks stock
Certification & stockpiling (25%)	Certification	5%	EMA certification	Full EMA certification,	Multi-state certification,	Single state certification,	Third-country certification,
	Industrial licensing	5%	Number of certified EU production sites	15+ certified sites	5–15 sites	<5 sites	No EU production sites
	Civil forecasting & planning	4%	Centralised EU-level procurement forecasting	Fully centralised EU forecasting	Partially centralised forecasting	National-only forecasting	No forecasting
	Military forecasting & planning	6%	Centralised EU-level procurement forecasting	Fully centralised EU forecasting	Bi-lateral forecasting and procurement	National-only forecasting	No forecasting
	Stockpile size & interoperability	5%	Combined civil & defence stockpiles (duration & interoperability)	>5 consumption weeks, Fully interoperable	3–5 consumption weeks, Partially interoperable	1–3 consumption weeks, Poor interoperable	Insufficient stock (<1 week) Non-interoperable
Deployment capacity (20%)	Civil first responder training	7%	National & EU first responder teams training programmes	All teams trained at NUTS 3 level	50% teams at NUTS 2 level	25% teams trained at NUTS 1 level	No teams with specialised training
	Military first responder training	7%	Military responder training at national & EU levels	All EU MS regiment responders trained	50% EU MS regiment responders trained	25% EU MS regiment responders trained	No training
	Logistics & deployment speed	6%	Delivery time for critical medical countermeasures	<40% of Time frame for medication	<75% Time frame for medication	<100% Time frame for medication	>100% Time frame for medication
	Crisis scenario testing & stress tests	4%	Regular EU-wide simulations & stress tests	Comprehensive EU-scale simulations Annual simulations	National exercises Biannual simulation	Local tests (Nuts scale) Infrequent exercise (min 1 each 5 year)	No regular crisis simulation

EMA: European Medicines Agency, NUTS: Nomenclature of territorial units for statistics and MS: Member-states.

Table 5. Simplified version of the technological sovereignty index for healthcare in defence. This reduced model distils Table 4 into a practical checklist of critical indicators. It is intended for rapid first-order assessments where data availability or resources are limited, offering policymakers a streamlined tool to evaluate sovereignty gaps before undertaking a full TSI assessment.

Dimension	Sub-dimension	Indicator	Institution concerned (and known dataset)
Research & development	Research output	Share of EU publications & patents across TRLs	Web of Science or Scopus (publications) EPO (database accessed via Orbit)
	Technology transfer agreements	Formal transfer agreements with EU industry	EMA
	R&D funding structure	Public, private, hybrid EU-based funding with anti-relocation clauses	HERA + DG RTD + EPO + DG GROW
	Training systems for researcher	Specialised training on CRBN medical countermeasures	DG RTD
	Research quality assessment	Independent evaluation cycles	European innovation scoreboard SCImago Country Ranking
	Technological Watch & Horizon Scanning	Active EU monitoring of disruptive innovations in the field	DG RTD or EFPIA
Industrial property, production & raw materials	Patent landscape	Share of non-EU patents & EU patent control	EPO
	Patent environment	Influence of the patent and number of litigations faced by the patent	EPO
	Licensing practices	Global & EU licensing activity | number of companies authorised to produce	EMA (EudraGMDP Dataset)
	Workforce & social resilience	Combined adaptability & social stability index (European Labour Authority)	Institute for economic and peace (global peace index) world economic forum (global competitiveness index)
	Localisation & control of critical manufacturing	Share of EU-based supply chains & production tools	EMA
	Raw material security & stockpiling	Source diversity, dependency & strategic reserves	EMA
Certification & stockpiling	Certification	Kind of EMA certification currently in use	EMA
	Industrial licensing	Number of certified EU production sites	EMA
	Unified procurement sovereignty	Public procurement legislative framework	HERA
	Public unified forecasting & planning	Administrative level used for procurement forecasting	HERA + Member-States preparedness agencies
	Stockpile quantity and quality	Combined civil & defence stockpiles (duration & interoperability)	HERA + MODs + MOHs
Deployment capacity	First responder training	Shares of first responders implied in training programmes	DG ECHO + MODs
	Logistics & deployment speed	Delivery time for deploy MCM	DG ECHO + UCPM + MODs
	Crisis scenario testing & stress tests	Size, deepness and frequency of simulation	DG ECHO + UCPM + MODs

EPO: European Patent Office. EMA: European Medicines Agency. DG GROW: Directorate-General for Internal Market, Industry, Entrepreneurship and SME. DG RTD: Directorate-General for Research and Innovation. EFPIA: European Federation of Pharmaceutical Industries and Associations. HERA: Health Emergency Preparedness and Response Agency. MODs: Ministries of Defence. MOHs: Ministries of Health. DG ECHO: Directorate-General for European Civil Protection and Humanitarian Aid Operations. UCPM: Union Civil Protection Mechanism.

MCDA implementation. Technological sovereignty in healthcare for defence encompasses multiple dimensions spanning fundamental research through to deployment. Maintaining control over critical infrastructures, secure supply chains and self-sufficiency in medical and biotechnological advancement constitute a determining factor in national security and public health resilience (Luzeaux, 2022). Recent initiatives, including Horizon Europe, the European Health Data Space and the Critical Raw Materials Act, seek to bolster Europe's biomedical innovation position whilst reducing external dependency (European Commission: Secretariat-General et al., 2023). A robust TSI must incorporate eight key dimensions: research, development, certification, production capabilities, raw material supply, civilian and military stockpiling and deployment capacity (Table 4). The research component assesses Europe's innovation capacity through R&D expenditure, patent filings, academic output in biomedical and defence technology and technology foresight capabilities (Desaunettes-Barbero et al., 2023). The development phase evaluates industrial R&D investments, strategic health sector start-ups and financial support mechanisms sustaining breakthrough innovations. Certification reflects regulatory agencies' capacity to independently assess and approve healthcare and defence innovations without external reliance. The European Medicines Agency and European Network for Health Technology Assessment play increasingly strategic roles in ensuring

that European standards remain both competitive and autonomous from non-EU regulatory bodies (Calderaro & Blumfelde, 2022). Production capacity assesses the ability to manufacture essential pharmaceuticals, vaccines and medical devices within Europe. The European Commission has recognised relocalising production's importance to mitigate supply chain vulnerabilities, particularly following COVID-19 disruptions (European Commission: Secretariat-General et al., 2023). Technological sovereignty is contingent upon raw material access, particularly in strategic sectors, including biotechnology, semiconductor-based medical devices and radiopharmaceuticals. Achieving sovereignty in certain domains presents substantial challenges. The semiconductor value chain exemplifies global integration complexity; despite hundreds of billions invested post-COVID to encourage advanced chip production relocation, many analysts consider total autonomy impossible, with China representing the notable exception of having made it a national priority following US measures blocking access to advanced components. Beyond production, storage capacity in both civilian and military contexts prove vital. Civilian stockpiling assesses the capacity to maintain reserves of essential medicines, vaccines and biotechnological products for crisis response. Military stockpiling focuses on ensuring strategic medical resource availability for defence operations, crisis response and bioterrorism preparedness. Finally, deployment capacity measures Europe's ability to efficiently distribute and mobilise health innovations during crises, evaluating logistics networks, emergency response coordination and supply chain adaptability under stress conditions.

The TSI methodology employs a multi-dimensional, lifecycle-based approach that captures sovereignty across four consolidated axes: research & development, industrial property, production & raw materials, certification & stockpiling, and deployment capacity. The scoring system (Table 4) structures assessment across four sovereignty levels: complete, partial, degraded and absent, offering a dynamic framework reflecting both capabilities and vulnerabilities. This approach enables granular tracking of strengths and weaknesses, providing nuanced assessment of Europe's autonomy in research control, intellectual property, manufacturing localisation and supply chain resilience. Table 4 details the full TSI operational framework, representing the transition from conceptual dimensions (Table 2) and aggregated axes (Table 3) to a structured model assigning measurable indicators, weights and sovereignty levels. The table organises into four main dimensions—research & development (25%), industrial property, production & raw materials (30%), certification & stockpiling (25%) and deployment capacity (20%). These weights reflect each dimension's relative importance in ensuring autonomy across the medical countermeasure lifecycle, from early research to crisis deployment. Within each dimension, sub-dimensions specify concrete sovereignty aspects. For research and development, sovereignty is assessed through six indicators: EU publications and patents shared across TRLs, technology transfer agreements with European industry, EU-based funding structures with anti-relocation clauses, specialised personnel training systems, independent research quality assessments and horizon scanning mechanisms. Each sub-dimension carries a weight proportional to its strategic relevance, defined through Work Package 2 of the COUNTERACT project (co-financed by the European Defence Fund), multiple stakeholder exchanges at HERA Industry Days (Brussels, June 2024) and the integration of work from the European Working Group on medical countermeasures for CBRN threat preparedness and response. For each indicator, Table 4 defines four graded sovereignty levels linked to measurable thresholds. 'complete sovereignty' in patent ownership corresponds to EU patents covering all TRLs, whilst 'Absent Sovereignty' reflects EU patent absence. Similarly, in production capacity, sovereignty is complete when 100% of supply chains and manufacturing tools are EU-based, whilst absent sovereignty reflects total non-EU infrastructure dependency. This scoring method provides a clear, transparent assessment of European control extent in each area. Table 4's analytical contribution lies in integrating heterogeneous elements—scientific output, industrial capacity, legal frameworks and operational preparedness—into a coherent evaluation grid. By combining weighted sub-dimensions with graded sovereignty thresholds, it enables composite scores calculation capturing both quantitative and qualitative technological sovereignty aspects. The structure proves flexible: weights can be adapted by decision-makers to reflect specific MCM criticality or emerging geopolitical priorities. Thus, Table 4 constitutes the TSI's methodological backbone, providing both a comprehensive diagnostic tool for identifying sovereignty gaps and a policy instrument guiding targeted interventions. The simplified version in Table 5 derives directly from this model, offering a rapid-assessment tool for cases with scarce data or requiring quick evaluations.

Results: application of the TSI on concrete cases

Although we are unable to disclose precise national or EU-wide scores owing to data confidentiality, security contingencies and geopolitical sensitivities, we can illustrate how the TSI structure supports informed assessment and strategic guidance. The index has been applied in simulation environments using anonymised input data and expert-derived estimations, which confirm its internal consistency and usefulness for sovereign capability mapping. For instance, if a Member State lacks on-shore production capacity for key biologicals, exhibits a high dependency on third-country certification and has no stockpiling capability, it would likely score 'degraded' or 'absent' on multiple axes of the TSI, significantly lowering the aggregated sovereignty score. Conversely, a jurisdiction that meets over 80% of its technological and production criteria through local or European infrastructure and maintains dual-use preparedness plans would approach. Yet, as several experts highlighted in our consultations, making such scores public—even in anonymised or illustrative form—could inadvertently expose critical weaknesses. This concern is not hypothetical. The European Commission's own guidance on dual-use technologies and critical infrastructure resilience stresses the imperative to balance transparency with strategic discretion. From an analytical standpoint, calculating the TSI at the national level would also reduce its relevance. Health defence innovation in Europe is characterised by distributed research, development and production, shared certification mechanisms and cross-border deployment strategies. Fragmenting the TSI by the Member State would ignore these interdependencies and potentially misrepresent vulnerability. Thus, the TSI is conceptually and operationally designed for EU-level application. Nonetheless, the index can inform national strategies by enabling Member States to benchmark their contributions to collective sovereignty and identify targeted investment areas—particularly in coordination with EU agencies. Future iterations of the TSI might incorporate protected-access dashboards to enable secure score visualisation for policymakers and regulators under appropriate confidentiality protocols.

Relevant institution and legal bases for a broader use

The operationalisation of the technological sovereignty index (TSI) requires access to reliable, verifiable and regularly updated data. While certain datasets are readily available—for example, scientific publications indexed in Scopus or Web of Science and patent applications registered at the European Patent Office (EPO)—other categories of information are far more sensitive. Production site data can be accessed through the European Medicines Agency's (EMA) EudraGMDP database, which publicly lists facilities compliant with good manufacturing practices (GMP). Similarly, indicators relating to research performance and innovation maturity are supported by pan-European benchmarks such as the European Innovation Scoreboard (Nepelski & Van Roy, 2021) and the SCImago Country Ranking (SCImago Journal & Country Rank, 2025). However, some data's, such as social resilience or research quality assessment data, are not linked to a single API or MCM and are assessed thanks to specific Index as Social Progress Index (The EU regional Social Progress Index 2.0., 2024). Thus, Table 5 inventories the dataset that are pertinent and the institution competent for each indicator. Conversely, highly strategic data—such as stockpiling levels of medical countermeasures (MCMs) or detailed supply chain dependencies—remain inaccessible to the public domain, as they are tightly regulated under Regulation (EC) No 726/2004 (2004) and Regulation (EU) 2022/123 (2025). These legal frameworks entrust the EMA and national competent authorities with monitoring responsibilities, but disclosure outside secure channels would risk undermining resilience. In this respect, initiatives by the European Health Emergency Preparedness and Response Authority (HERA) and the European Defence Agency (EDA) are crucial, as they provide the institutional foundations for confidential data collection, coordination and structured cooperation between civil and defence actors. Thus, the broader application of the TSI relies on a hybrid model of data governance: open-access indicators for transparency and benchmarking, complemented by restricted datasets accessible only within secured institutional frameworks. This dual-track system reflects both the sensitivity of defence-related information and the EU's ambition to ensure strategic autonomy without compromising collective security.

Calculation of the TSI: from raw data to index

Once the relevant datasets are collected, each indicator is classified along four categories of sovereignty: complete, partial, degraded or absent. A proportional score is attributed to each classification, following a

linear calculation method. This choice, as opposed to logarithmic alternatives, ensures transparency and facilitates understanding of the direct relationship between indicators and the final index. When data for a specific indicator are missing, the median of equivalent EU-level data is applied as a proxy, thereby maintaining coherence and comparability across Member States. Each section is then aggregated according to its strategic relevance coefficient, with the results converted into percentages. Sovereignty levels are defined as: (1) complete sovereignty for values >90%; (2) partial sovereignty between 65%–90%; (3) degraded sovereignty between 25%–65% and (4) absent sovereignty for values <25%. The aggregation across dimensions produces an overall sovereignty index while also highlighting specific vulnerabilities. For instance, an MCM may demonstrate strong sovereignty in research & development but remain critically dependent on external suppliers for raw materials, undermining overall resilience. By identifying these weakest links, the TSI provides decision-makers with actionable insights for targeted investments and regulatory measures, in line with EU objectives on open strategic autonomy. In areas such as vaccine research, the EU has demonstrated high sovereignty scores in R&D and regulatory certification, supported by the EMA's centralised procedures and Horizon Europe's funding of biomedical innovation. However, sovereignty scores fall significantly in Production & Raw Materials, reflecting persistent dependency on non-EU suppliers for active ingredients, adjuvants and critical biotechnological inputs. This mirrors findings from the European Commission's Critical Raw Materials Act (2024), which identified over 90% import reliance for certain components essential to biomedical and digital technologies. Conversely, in the domain of diagnostic reagents, the EU exhibits stronger industrial sovereignty because of localised SME production and shorter supply chains. Nevertheless, vulnerabilities remain in digital layers of the value chain—particularly in cloud-based health data infrastructures—where dependence on U.S. service providers exposes European actors to extraterritorial legislation such as the U.S. Cloud Act, stressing the importance of integrating data sovereignty within the health innovation ecosystem. However, only the relevant European agencies currently have the capacity and authorisation to collect all the data necessary to calculate the TSI. Nevertheless, the purpose of this manuscript is to provide an academic demonstration of the strategic interest of such an index. Finally, the publication of minimally sensitive data concerning medical countermeasures against CRBN threats would imply the possible highlighting of weaknesses in civilian and military systems. This would constitute an ethical issue. Indeed, between the undeniable functioning of open contradictory discussions in the academic world, the need for transparent and democratic governance of member states and the European Union, but also the absolute necessity of protecting weaknesses, the limit of what is, or should be, openly publishable is undoubtedly debatable.

Discussion

The establishment of a technological sovereignty index for health innovation in defence is imperative given the vulnerabilities exposed by recent crises. The COVID-19 pandemic highlighted Europe's acute over-reliance on external suppliers for essential medical products, whilst the war in Ukraine exposed fragilities in European industrial supply chains directly linked to military resilience, demonstrating the inherent interdependence between health security and defence readiness (Linkov et al., 2020). These converging crises underscore the urgency of developing structured assessment tools capable of identifying sovereignty gaps across the full innovation-to-deployment lifecycle. The TSI addresses this need by providing actionable intelligence for each actor across the medical countermeasure supply chain and all implicated public bodies—from research sponsors to stockpiling authorities and end-users. The wide range of actors involved necessitates a decentralised and incremental approach whereby each stakeholder contributes relevant data corresponding to their position within the MCM lifecycle. This distributed governance model reflects the complexity inherent in composite indices and requires that incremental evaluation be adapted by competent stakeholders to the technological, economic and territorial realities specific to each MCM (Darnis, 2021). The relative weights in Table 4 should remain adaptable to specific contexts whilst maintaining consistency with the TSI's overarching objectives. Table 5 provides a simplified entry point for preliminary assessments, enabling rapid sovereignty gap identification before comprehensive TSI evaluation. A steering committee comprising relevant EU and national agencies could facilitate coordination, ultimately enabling assessment of European preparedness through a whole-of-domain approach (Ninistö, 2024).

Policy implications and strategic recommendations

This research offers actionable policy recommendations grounded in the TSI framework. Structured identification of sovereignty gaps through measurable indicators enables targeted investments in biomanufacturing capacity, regulatory infrastructure and strategic stockpiling. Policymakers should prioritise domains scoring as 'degraded' or 'absent', representing systemic vulnerabilities—particularly salient given recent disruptions (Linkov et al., 2020). Based on simulated TSI applications using anonymised expert-derived estimations, we recommend establishing an EU-level 'Strategic Sovereignty Fund for Health Innovation' to co-finance investments in areas below critical thresholds, analogous to resilience funding mechanisms in critical infrastructure sectors. This fund could integrate existing EU instruments such as the EU FAB initiative, rescEU, the European Defence Fund, or HERA's incubator programmes whilst operating under a sovereignty-centred evaluation framework ensuring that investments address capability gaps systematically. Decision-makers would find this research operationally useful in three complementary ways. First, it offers a harmonised methodology to assess health innovation ecosystem strategic maturity in real-time, enabling evidence-based priority-setting across complex, multi-actor environments. Second, the TSI facilitates horizontal coordination between defence, health and industry stakeholders through a shared sovereignty metric—a coordination mechanism currently absent from most national strategies (Linkov & Kott, 2025). By providing common analytical language, the TSI reduces fragmentation and supports coherent cross-sectoral policy development. Third, the index can inform scenario planning exercises and cross-border joint programmes, enabling Member States to anticipate vulnerabilities under different geopolitical or public health crisis scenarios whilst identifying opportunities for collaborative capacity-building (Belton & Stewart, 2002). Regarding anticipated effects of implementing TSI-driven strategies, existing MCDA-based evaluations in analogous domains—including cyber-resilience, energy autonomy and pharmaceutical supply chain security—suggest that targeted interventions in weakly scored dimensions yield significant returns on investment in terms of both strategic autonomy and operational resilience (Belton & Stewart, 2002). Improved TSI scores are likely to enhance EU autonomy, reduce crisis response times, strengthen supply chain redundancy and bolster technological competitiveness in global markets. Similar MCDA-informed frameworks are already embedded within EU-wide digital infrastructure policy, as evidenced by the European Digital Compass 2030, underscoring the practical feasibility of integrating TSI logic into public policy architecture at the European level (Commission to the European Parliament et al., 2021).

Constraints on empirical disclosure and the rationale for EU-level application

Whilst we cannot disclose precise national or EU-wide TSI scores owing to data confidentiality constraints and geopolitical sensitivities, we can illustrate how the TSI structure supports informed strategic assessment. The index has been applied in simulation environments using anonymised input data and expert-derived estimations, confirming its internal consistency and utility for sovereign capability mapping. For instance, a Member State exhibiting limited on-shore production capacity for key biologicals, high dependency on third-country certification pathways and insufficient stockpiling capabilities would likely score 'degraded' or 'absent' across multiple TSI axes, significantly lowering the aggregated sovereignty score. Conversely, a jurisdiction meeting over 80% of its technological and production criteria through domestic or European infrastructure whilst maintaining integrated dual-use preparedness plans would approach 'complete sovereignty' thresholds. However, as experts emphasised during HERA Industry Days consultations and within the European working group on CBRN medical countermeasures, making such scores publicly accessible—even in anonymised or illustrative form—could inadvertently expose critical vulnerabilities to adversarial scrutiny. This concern is not hypothetical: the European Commission's own guidance on dual-use technologies and critical infrastructure resilience stresses the imperative to balance transparency with strategic discretion in sensitive defence and health domains. From an analytical standpoint, calculating the TSI at the national level would also diminish its relevance. Health innovation in Europe is characterised by distributed research ecosystems, cross-border development and production networks, shared certification mechanisms and multinational deployment strategies. Fragmenting the TSI by the Member State would ignore these interdependencies and potentially misrepresent collective

vulnerability profiles. Thus, the TSI is conceptually and operationally designed for EU-level application, reflecting the reality of pooled sovereignty in health security and defence preparedness. Nonetheless, the index can inform national strategies by enabling Member States to benchmark their contributions to collective European sovereignty and identify targeted investment areas—particularly in coordination with EU agencies, including HERA, EDA, EMA and ECDC. Future iterations might incorporate protected-access dashboards enabling secure score visualisation for policymakers and regulators under appropriate confidentiality protocols, balancing strategic transparency with operational security imperatives.

Methodological robustness and legal considerations

Technological sovereignty requires an integrated understanding of the interplay between scientific excellence, regulatory autonomy, industrial resilience and supply chain security. The TSI's robustness could be further improved by addressing certain legal provisions in industrial protection frameworks that may inadvertently undermine sovereignty objectives. Notably, the unitary patent system, whilst designed to streamline cross-border patent protections, introduces structural vulnerabilities: a national prior application can invalidate an entire unitary patent rather than affecting only a single territory. This 'poisoned unitary effect' creates strategic risks for European patent applications that could impair TSI scores in the Industrial Property dimension (Desaunettes-Barbero et al., 2023). Policymakers should consider reforms to harmonise patent protection mechanisms in ways that reinforce rather than compromise technological sovereignty. Traditional innovation indicators—typically emphasising aggregate R&D expenditure, patent volumes, or collaborative research outputs—prove insufficient when applied to health innovation with direct defence relevance. The challenge extends beyond merely generating intellectual property within Europe; it encompasses ensuring that the industrial, regulatory and logistical ecosystems necessary to translate technological advances into deployable capabilities remain anchored within the Union's territory and governance frameworks. The TSI addresses this gap by embedding operational readiness, supply chain localisation and regulatory autonomy as core evaluation criteria alongside innovation capacity. The index also helps address persistent fragmentation between civilian and defence innovation ecosystems. Health innovation within the civilian sphere, largely supported through Horizon Europe and national health research programmes, rarely engages directly with defence-specific requirements such as field trauma management, biothreat preparedness, or medical countermeasures for operational deployment. Conversely, defence health needs are often addressed through isolated initiatives under the European Defence Fund or ad hoc EDA projects, resulting in duplicated efforts and missed opportunities for dual-use development. By providing a unified sovereignty assessment framework spanning both civil and military dimensions, the TSI encourages strategic alignment and resource optimisation across these traditionally siloed domains.

Broader applicability and ethical dimensions

The TSI's importance extends beyond the defence sector. Health sovereignty in civilian domains faces analogous challenges, with Europe's dependence on imported biological materials providing a particularly illustrative case. According to data from the Établissement Français du Sang, approximately 60% of the plasma used in France for plasma-derived medicinal products originates from the United States (Rapport d'Activité, 2023). This heavy reliance on non-European biological materials exposes Europe not only to supply disruptions during crises but also to potential geopolitical leverage over critical health infrastructure. A TSI adapted for civilian health applications could identify such dependencies systematically and guide investments in domestic plasma collection infrastructure and fractionation capacity. The proposed TSI must remain dynamic and adapt to changes in international regulatory frameworks. Currently, MCMs are classified as medicines and thus exempt from national and international legislation governing weapons import and export, including ITAR/EAR regulations and other extraterritorial legislative frameworks. However, owing to their potential role in current or future conflicts, MCMs or their components could be subjected to unilateral regulatory reclassification by individual states, fundamentally altering their TSI profiles. A comprehensive de-risking approach incorporating regular horizon scanning and regulatory foresight would be required to adapt TSI assessments accordingly, ensuring that

the index remains relevant under evolving geopolitical conditions. The health innovation for defence sector presents unique challenges by conjugating two inherently sensitive domains—health and defence—which significantly complicates data visibility and hampers comprehensive situational assessment. Operationalising the TSI will require substantial coordination between agencies, public bodies and private sector actors, particularly given the complexity of military/civilian and national/European institutional landscapes. The tool's intended breadth—spanning research through operational deployment—further complicates assessment by involving numerous stakeholders at each lifecycle stage. The main weakness of the TSI remains the substantial challenge of acquiring relevant sensitive and classified data. At each MCM lifecycle stage, need-to-know protocols must be established by relevant public agencies to implement each TSI dimension whilst respecting security requirements. The gap between the information ideally required versus the current level of data sharing amongst trusted partners within the key TSI dimensions represents perhaps the most critical issue to be addressed for full operationalisation. Crucially, implementing a TSI for health innovation in defence offers an opportunity to embed ethical governance principles directly into the evaluation framework, thereby reinforcing Europe's normative leadership in health innovation governance. The index could incorporate indicators assessing the ethical sourcing of raw materials, including human biological materials such as plasma, ensuring full traceability and adherence to European ethical standards. Such integration would distinguish the European approach from competitors operating under different normative frameworks, positioning the EU as a global standard-setter in ethically grounded technological sovereignty. The broader literature has increasingly highlighted technological sovereignty's growing importance as a foundational pillar of European strategic autonomy (Howoldt & Borrás, 2023). Recent analyses stress that sovereignty in critical technologies, including health innovation, is now recognised as an essential precondition for Europe's ability to navigate geopolitical tensions, assert regulatory leadership and preserve its industrial base against external economic coercion (Csernatoni, 2022).

Conclusion

The examination of technological sovereignty within the European health innovation ecosystem, particularly when linked to defence preparedness, highlights the urgency of reducing the EU's external dependencies across the full innovation-to-deployment cycle. The COVID-19 pandemic exposed severe vulnerabilities in European capacity to secure essential medical countermeasures, whilst the war in Ukraine revealed the geopolitical fragility of relying on third-country technologies for critical infrastructure. When applied to defence health innovation, these risks multiply, as military operational readiness depends directly on the secure and timely availability of advanced medical diagnostics, treatments, vaccines and biodefence capabilities. The proposed TSI, tailored specifically to the health and defence intersection, offers a pragmatic and dynamic tool to monitor, assess and anticipate the EU's strengths and vulnerabilities in this domain. Unlike standard R&D or innovation metrics, the TSI embeds regulatory sovereignty as a core dimension, reflecting the EU's ability to develop, authorise and rapidly deploy strategic medical technologies without requiring validation from non-European regulatory bodies or private companies. Regulatory autonomy, particularly in crises involving biological or chemical threats, is essential to ensuring that European forces and civilian populations benefit from rapid, independent decision-making on the authorisation and use of medical countermeasures, free from geopolitical influence. The synergy between HERA and the European Defence Agency plays a pivotal role in this framework. HERA's mandate to anticipate, coordinate and stockpile critical medical products aligns directly with EDA's efforts to enhance defence readiness through technology foresight, capability development and scenario planning. However, effective governance of health for defence of technological sovereignty also depends on closer cooperation with the European Medicines Agency for accelerated regulatory processes, the European Innovation Council for funding disruptive medical technologies with dual-use potential and HERA/ECDC for intelligence and surveillance of emerging biological threats. A coherent governance framework, supported by a sovereignty monitoring instrument like the TSI, would enhance Europe's capacity to align research investments, regulatory frameworks, supply chain strategies and military planning, ensuring that technological autonomy is embedded at every stage.

Embedding technological sovereignty into the governance of European health innovation for defence strengthens not only the Union's strategic autonomy but also its credibility as a reliable security provider within both EU-level crisis response mechanisms and NATO frameworks. By ensuring that Europe retains independent access to strategic health technologies, the EU can better protect its populations and armed forces whilst reinforcing its position as a global leader in dual-use innovation and health security governance. This holistic approach—bridging industrial policies, research funding, regulatory capacity and operational preparedness—would transform technological sovereignty from a reactive ambition into a structural pillar of European resilience. Furthermore, embedding the TSI in EU decision-making would reinforce coherence between industrial policy, regulatory frameworks and crisis preparedness, enabling the Union to detect sovereignty gaps and design proactive responses. Importantly, such an index could also integrate ethical dimensions, such as the traceability of biological materials, in order to maintain Europe's role as a normative leader in global health governance. The European Union, the Member States and the states associated with common European defence must change their perception of their technological sovereignty by delimiting the responsibilities of each to streamline the exchange of strategic information and thus develop complementary national and European sovereignties.

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