Review Article
ISSN: **3051-8830**
Journal homepage: https://www.harrisonacademicpress.com/index.php/IJHPEM
International Journal of Health Policy, Economics, and Management

Harrison Academic Press

Regulatory Harmonisation of Digital Health Applications Across the European Union: A Comparative Policy Study

Matic K[1*], Nikolaou M[2] and Dvorak M[3]

[1]*Department of Health Policy, University of Zagreb, Zagreb, Croatia*
[2]*Department of Health Informatics, Aristotle University of Thessaloniki, Thessaloniki, Greece*
[3]*Department of Public Administration, Charles University, Prague, Czech Republic*

ABSTRACT

Background: Digital health applications, including software as a medical device and reimbursable digital therapeutics, are subject to a layered European Union (EU) regulatory environment in which device-level rules are formally harmonised while reimbursement and cross-border data governance remain largely national competences. Objective: This review compares the state of regulatory harmonisation across three domains - device classification and market access under the Medical Device Regulation (MDR) and the Artificial Intelligence Act, national reimbursement and health technology assessment (HTA) pathways, and cross-border interoperability under the European Health Data Space (EHDS) - to identify where EU-wide convergence has been achieved and where fragmentation persists. Methods: A narrative comparative policy review synthesised peer-reviewed literature identified through targeted searches of PubMed/MEDLINE and Crossref-indexed journals, with each candidate source individually verified against its publisher or Crossref bibliographic record before inclusion; sources were organised thematically across the three domains, comparing Germany's DiGA pathway, France's PECAN scheme, Belgium's mHealthBELGIUM validation pyramid, and the United Kingdom's NICE Evidence Standards Framework. Findings: The MDR provides substantial, directly applicable harmonisation of device classification and CE marking, though notified body capacity constraints produce uneven implementation across member states; the emerging AI Act adds a further, only partially reconciled conformity layer for AI-enabled products. Reimbursement remains the least harmonised domain, with Germany, France, Belgium, and the United Kingdom each applying structurally distinct evidentiary and financing models despite shared underlying MDR classification. The EHDS represents an ambitious attempt to harmonise cross-border data interoperability, but its legal ambition currently outpaces the technical and institutional readiness of privacy-enhancing technologies and federated data infrastructure across member states. Conclusions: EU harmonisation of digital health applications is progressing unevenly across three largely independent axes - device classification, reimbursement, and data interoperability - each requiring distinct policy benchmarks and further investment in implementation capacity rather than legal text alone.

Keywords: *digital health regulation; Medical Device Regulation; European Health Data Space; digital therapeutics reimbursement; health technology assessment*

Citation: Matic K, Nikolaou M and Dvorak M (2026) Regulatory Harmonisation of Digital Health Applications Across the European Union: A Comparative Policy Study. Int J Health Policy Econ Manag, 4(1): 01-07.
DOI: 10.5281/zenodo.22661484

Corresponding Author: *Karlo Matic*

E-mail Address: *karlo.matic@universityofzagreb.edu*

Article History: *Received 5 January 2026 | Accepted 26 March 2026 | Published 16 June 2026*

Copyright: *© 2026 Karlo Matic, et al. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited (**https://creativecommons.org/licenses/by/4.0/**).*

Introduction

Digital health applications — mobile apps, browser-based platforms, and software-only diagnostic or therapeutic tools that qualify as software as a medical device (SaMD) — have moved from pilot projects to reimbursed, prescribable clinical interventions across parts of the European Union in less than a decade. Germany's Digitale Gesundheitsanwendungen (DiGA) fast-track pathway, introduced in 2019 and operational since 2020, has become the most visible example of a national reimbursement route built specifically for digital therapeutics, and by mid-decade several dozen applications had been permanently or provisionally listed in the DiGA directory [1,2]. France followed with the Prise En Charge Anticipée Numérique (PECAN) early-access scheme, Belgium introduced its mHealthBELGIUM validation pyramid linking evidence maturity to financing tiers, and the United Kingdom's National Institute for Health and Care Excellence (NICE) published an Evidence Standards Framework specifically calibrated to the evidentiary realities of software interventions rather than pharmaceuticals [3,4]. Each of these national instruments was designed to solve a genuine problem — the absence of a coherent evidentiary and

reimbursement route for low-risk, iteratively updated software products — but each was also designed independently, using different risk classifications, different clinical evidence thresholds, different pricing mechanisms, and different definitions of what counts as a "digital therapeutic" at all.

This national proliferation sits uneasily against the European Union's own regulatory architecture for medical devices, which is nominally harmonised. Regulation (EU) 2017/745, the Medical Device Regulation (MDR), applies uniformly across member states and explicitly extends the definition of a medical device to qualifying standalone software, subjecting many digital health applications to CE-marking obligations, clinical evaluation requirements, and post-market surveillance duties that did not exist, or were far lighter, under the preceding Medical Device Directive [5,6]. In principle, a single CE mark should allow a compliant digital health application to be placed on the market anywhere in the Union. In practice, CE marking under the MDR establishes only a safety and performance floor; it says nothing about whether a national payer will reimburse the product, at what price, on the basis of what clinical evidence, or through what administrative pathway. The result is a two-layer regulatory structure in which market access is harmonised at the EU level while reimbursement access remains almost entirely a national competence, and it is at this second layer that the fragmentation this review examines is concentrated [7,8].

Layered on top of this MDR/reimbursement divide is a second, more recent harmonisation project: the European Health Data Space (EHDS), formally adopted to create common rules for both the primary use of electronic health data (patients accessing and sharing their own records across borders) and its secondary use for research, innovation, and policymaking [9]. The EHDS is explicitly framed as an interoperability and data-governance instrument rather than a medical device or reimbursement instrument, yet its success is functionally entangled with digital health application regulation, because many of the highest-value SaMD products — AI-assisted diagnostic tools, remote monitoring platforms, digital therapeutics that adapt to longitudinal patient data — depend on exactly the kind of cross-border, interoperable data access the EHDS is meant to enable [10,11]. A digital health application that is CE-marked under the MDR, reimbursed under a national DiGA-equivalent scheme, but unable to exchange structured patient data across a border because national data protection implementations diverge, illustrates precisely the layered, only-partially-harmonised regulatory environment that manufacturers, health systems, and patients currently navigate [12].

This review asks a comparative policy question: across the domains of device classification and market access, national reimbursement and health technology assessment (HTA) pathways, and cross-border data governance, where has the European Union achieved genuine regulatory harmonisation for digital health applications, and where does meaningful fragmentation persist despite a shared legal framework? We synthesise the peer-reviewed comparative policy, health services research, and legal-analytical literature addressing these three domains, with attention to how the emerging EU AI Act intersects with existing MDR obligations for AI-enabled SaMD, and to what comparative national experience — principally Germany, France, Belgium, and the United Kingdom (retained here as a comparator given its structural proximity to EU frameworks) — suggests about the feasibility of further harmonisation.

Methods

This is a narrative comparative policy review rather than a systematic review with a registered protocol, reflecting a topic that spans health law, health technology assessment methodology, and health informatics governance and for which a single quantitative outcome measure does not exist. Relevant literature was identified through targeted searches of PubMed/MEDLINE, Crossref-indexed journals, and publisher databases (Nature/npj Digital Medicine, Frontiers, SAGE, Elsevier, JMIR) using combinations of terms including "Medical Device Regulation," "software as a medical device," "digital therapeutics," "DiGA," "PECAN," "health technology assessment," "European Health Data Space," "interoperability," "cross-border health data," and "AI Act medical device." Candidate sources were restricted to peer-reviewed journal articles, and each candidate was individually verified against its publisher or Crossref bibliographic record — title, full author list, journal, volume/issue, pagination or article number, and DOI — before inclusion; sources that could not be independently verified through a live bibliographic lookup were excluded rather than cited from memory or a plausible-sounding title alone. Sources were then organised thematically into three domains structuring the Findings section: (1) EU-level device classification and market-access harmonisation under the MDR and its interaction with the AI Act; (2) national reimbursement and health technology assessment pathways for digital therapeutics, compared across Germany, France, Belgium, and the United Kingdom; and (3) cross-border interoperability and data governance harmonisation under the European Health Data Space and the General Data Protection Regulation (GDPR). Because this is a narrative synthesis rather than a systematic review, no formal risk-of-bias appraisal or meta-analytic pooling was performed, and quantitative figures drawn from individual studies are presented as illustrative of documented patterns rather than as pooled estimates.

Regulatory Harmonisation at the Device Level: The Medical Device Regulation and the AI Act

The MDR represents the EU's most complete harmonisation achievement in this space: a single regulatory text, directly applicable across all member states without transposition, that establishes uniform classification rules, conformity assessment procedures, and post-market obligations for qualifying standalone software. Classification under MDR Rule 11 assigns software to risk classes (I, IIa, IIb, or III) according to the significance of the information it provides for diagnosis or therapy and the criticality of the condition addressed, and systematic reviews of manufacturers' experience navigating this rule find that the classification step itself, together with the associated clinical evaluation and post-market surveillance obligations, has substantially raised the regulatory burden on digital health developers relative to the prior directive-based regime, particularly for small and medium-sized enterprises with limited regulatory affairs capacity [5]. Empirical analysis of the MDR's practical impact on digital health manufacturers specifically documents that notified body capacity constraints, combined with the requirement for many previously self-certified or lower-class software products to undergo full conformity assessment for the first time, have lengthened time-to-market and, in some cases, driven smaller developers to withdraw products or delay EU launches altogether — an unintended consequence of stricter harmonisation that manufacturers report as more disruptive than the classification criteria themselves [6].

This finding is significant for the harmonisation question this review addresses: the MDR succeeds in creating one legal standard, but the capacity to apply that standard uniformly and promptly across the notified body ecosystem is itself unevenly distributed, producing a form of de facto fragmentation even where the de jure rule is single and uniform.

Comparative harmonisation status of major EU-level instruments governing digital health applications, by regulatory domain.

Instrument	Regulatory domain	Legal harmonisation status	Documented implementation gap	Key reference
Medical Device Regulation (EU 2017/745)	Device classification and market access	Directly applicable, uniform classification rules across member states	Notified body capacity constraints lengthen time-to-market, especially for SMEs	Svempe 2026
EU Artificial Intelligence Act	AI-enabled SaMD conformity assessment	Directly applicable, but only partially reconciled with MDR clinical evaluation	Dual documentation burden; coordination across MDCG, AI Office, and national authorities still maturing	Aboy et al. 2024
European Health Data Space	Cross-border data interoperability (primary and secondary use)	Directly applicable EU regulation withcommon interoperability toolkit	Federated analysis and privacy-enhancing technology infrastructure remain technically immature in several member states	van Drumpt et al. 2025
GDPR (secondary use provisions)	Legal basis and safeguards for health data reuse	Directly applicable regulation, but broad discretion left to national authorities	National data protection authorities interpret research/public-interest bases inconsistently	Vukovic et al. 2022

A second and more recent harmonisation challenge arises from the interaction between the MDR and the EU Artificial Intelligence Act, which layers an additional risk-classification and conformity regime onto AI-enabled digital health products that in many cases already qualify as medical devices under the MDR. Comparative legal analysis of this overlap finds that AI-enabled SaMD manufacturers must now satisfy two parallel, only partially aligned regulatory logics — MDR clinical evaluation focused on safety and performance, and AI Act conformity assessment focused on data governance, transparency, and human oversight — with the two frameworks sharing some notified body infrastructure but applying distinct documentation and lifecycle-monitoring requirements that are not yet fully reconciled in implementing guidance [13]. Mapping exercises of the broader EU regulatory landscape for health AI similarly conclude that, while both the MDR and the AI Act are formally harmonised instruments, the practical governance of AI-enabled health technologies remains distributed across multiple EU bodies (the Medical Device Coordination Group, the AI Office, and national market surveillance authorities) whose coordination mechanisms are still maturing, such that a manufacturer's actual compliance pathway can still differ meaningfully depending on which member state's notified bodies and market surveillance authorities are engaged first [14]. Table 1 summarises how harmonised, in practice, each of the major EU-level instruments reviewed here is along the device-classification and market-access dimension, contrasted with the reimbursement and data-governance dimensions addressed in the sections that follow.

National Fragmentation in Reimbursement and Health Technology Assessment Pathways

Where the MDR achieves substantial (if imperfectly implemented) harmonisation at the level of market access, reimbursement remains almost entirely a national competence, and the comparative HTA literature documents genuinely divergent pathways even among member states with broadly similar health system structures. Germany's DiGA pathway allows a CE-marked, low-risk digital health application to obtain provisional listing and reimbursement for up to twelve months based on a plausible case for "positive healthcare effects," with permanent listing conditional on demonstrating this effect in a comparative study within that window; detailed analysis of the DiGA directory finds substantial heterogeneity in the evidentiary rigor manufacturers actually submit, with a meaningful share of permanently listed applications relying on study designs and effect measures that fall short of the standard the pathway's own guidance documents describe as ideal [2]. A systematic review of the accumulated three-year evidence base for reimbursed DiGA products similarly finds that outcome robustness varies substantially by indication and that the fast-track model's core trade-off — rapid conditional access in exchange for deferred, sometimes incomplete, confirmatory evidence — has produced a reimbursed product landscape in which patient-relevant benefit is more firmly established for some applications than others [15]. Longitudinal analysis of the scheme's first three years of operation similarly documents a pathway that has evolved substantially since 2020 in response to observed gaps, including tightened evidence requirements and a growing role for post-listing real-world data collection, indicating that the German model itself remains a moving target for other member states attempting to benchmark against it [1].

Structural comparison of national and comparator reimbursement/health technology assessment pathways for digital therapeutics.

Country/scheme	Core mechanism	Evidence model	Documented limitation	Key reference
Germany (DiGA)	Provisional listing (up to 12 months) converting to permanent listing	Plausible healthcare-effect case, then comparative study for permanent listing	Heterogeneous evidentiary rigor among permanently listed applications	Mäder et al. 2023
France (PECAN)	Time-limited early access with real-world data collection	Real-world data generated during early access informs subsequent HTA decision	Distinct mechanics from DiGA limit direct evidence transferability	Lievevrouw et al. 2024

Country/scheme	Core mechanism	Evidence model	Documented limitation	Key reference
Belgium (mHealthBELGIUM validation pyramid)	Graduated financing tiers (M1-M3) tied to evidence maturity	Escalating clinical and economic evidence required for higher reimbursement tiers	Nationally idiosyncratic ladder despite explicit reference to EU/German precedent	Lievevrouw et al. 2024
United Kingdom (NICE Evidence Standards Framework)	Functional tiering (understanding, communicating, self-management, treatment)	Evidence expectations calibrated to technology function and risk	Distinct classification logic from continental provisional-listing or tier models	Unsworth et al. 2021

France's PECAN early-access scheme was explicitly designed with partial reference to the German precedent but layers a distinct evidence-generation logic, requiring digital medical devices to enter a time-limited early-access period during which a national reimbursement agency collects real-world data to inform a subsequent conventional HTA decision, an arrangement broadly comparable in intent to, but structurally distinct in mechanics from, the DiGA model. Belgium's mHealthBELGIUM validation pyramid pursues yet a third logic, tying a graduated set of financing tiers (M1 through M3) to escalating levels of demonstrated clinical and economic evidence, with only the highest tier eligible for full reimbursement; qualitative policy analysis of the Belgian scheme's development documents that it was constructed in explicit, deliberate reference to both German and broader EU digital health policy discourse, yet still produced a nationally idiosyncratic evidentiary ladder rather than converging on a shared European evidence standard [3]. The United Kingdom's NICE Evidence Standards Framework, while outside the EU since Brexit, remains an influential comparator because it was developed contemporaneously with these EU national schemes and pursues a functionally similar goal — calibrating evidence expectations to the risk and function of the digital health technology in question — through a tiered classification of technologies by function (understanding, communicating, informing self-management, delivering treatment) rather than the accumulation-toward-a-financing-tier model used in Belgium or the provisional-to-permanent listing structure used in Germany [4].

Direct three-country comparative analysis of the German, UK, and French HTA approaches to digital therapeutics finds that all three systems now formally require comparative clinical evidence before durable reimbursement, but differ substantially in the type of comparator required, the acceptable minimum duration and design of pivotal studies, and the weight given to patient-reported and real-world evidence relative to randomised trial data — differences substantial enough that a manufacturer conducting a single pivotal trial designed to satisfy one country's evidentiary bar frequently finds it insufficient, without supplementary evidence generation, to satisfy another's [8]. Broader synthesis work explicitly aimed at "harmonising" assessment and reimbursement of digital medical devices across the EU concludes that mutual learning between national HTA bodies is occurring — reflected in shared terminology, occasional cross-referencing of evidentiary frameworks, and early-stage cooperation through EU HTA coordination mechanisms — but that this mutual learning has not yet produced a common evidentiary standard or joint assessment procedure comparable to what the MDR achieves for market access, leaving reimbursement the primary axis along which meaningful fragmentation persists [7]. Multi-country analysis of approved digital therapeutic product characteristics across jurisdictions reinforces this picture empirically, finding that the clinical indications, evidence packages, and approval timelines of digital therapeutics reaching national reimbursement lists vary enough across the compared countries that a common EU-level product category is not yet observable in practice, notwithstanding the shared MDR classification underlying nearly all of the products compared [16]. Complementary synthesis of the broader European adoption landscape similarly finds substantial cross-country variation in the pace and structure of digital therapeutics uptake even where formal reimbursement pathways nominally exist, attributing this variation as much to differences in prescriber familiarity, clinical guideline integration, and patient digital literacy as to the formal regulatory instrument itself [17]. Table 2 summarises the structural differences among the four national/comparator reimbursement pathways reviewed here.

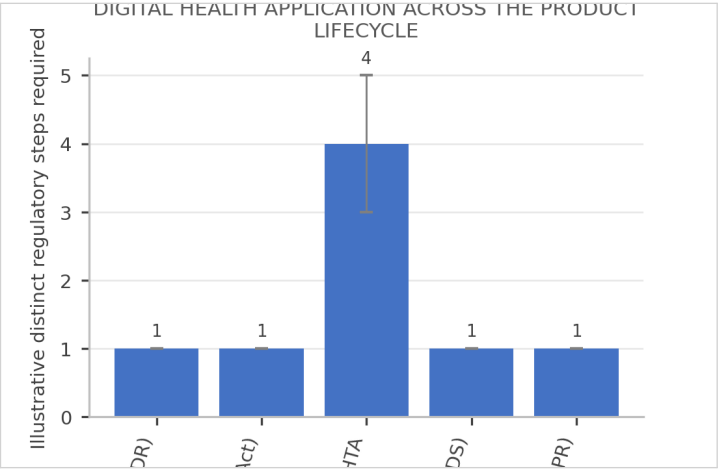
Cross-Border Interoperability and Data Governance: The European Health Data Space

The third domain in which harmonisation is being actively pursued, and where its outcome is least settled, concerns the data infrastructure that increasingly determines whether a digital health application can function equivalently across borders at all. The European Health Data Space establishes, for the first time, EU-wide legal obligations for both primary use (patient access to and portability of their own electronic health data across member states) and secondary use (research, innovation, and public-health access to health data under defined safeguards), and detailed analysis of its interoperability provisions finds that the EHDS explicitly builds on the pre-existing European Interoperability Framework, translating high-level interoperability principles into a standards-compliance toolkit intended to give AI-driven and other digital health projects a concrete pathway to demonstrable, auditable data interoperability rather than an aspirational goal alone [9]. This is a substantial harmonisation ambition, because it targets precisely the technical layer — data format, semantic and legal interoperability — that has historically undermined cross-border functioning of even fully CE-marked, nationally reimbursed digital health products.

Analysis focused specifically on telemedicine platforms under the EHDS documents that the regulation is explicitly framed as enabling a "new paradigm" for cross-border remote care by requiring member states to support structured, interoperable exchange of core patient data categories (patient summaries, e-prescriptions, laboratory results, medical imaging, and discharge reports) through a common cross-border infrastructure, addressing a gap that earlier cross-border healthcare directives left largely unresolved in practice [11]. However, research specifically examining the secondary-use provisions of the EHDS and their interaction with privacy-enhancing technologies finds that, while the regulation establishes a legal obligation for health data access bodies to make data available for approved secondary uses, the practical mechanisms by which this is to be achieved — federated analysis, synthetic data generation, secure processing environments — remain at an early and heterogeneous stage of technical maturity across member states, such that legal harmonisation is, at least for now, running ahead of the technical infrastructure needed to

realise it uniformly [10]. This is analogous to the notified-body capacity gap identified in the MDR context: a single legal instrument does not guarantee uniform operational capability.

Illustrative count of distinct national and EU-level regulatory instruments a digital health application typically must satisfy to achieve market access, national reimbursement, and cross-border data interoperability, synthesized from the comparative policy literature reviewed (Tarricone et al., 2024; van Drumpt et al., 2025; Lalova-Spinks et al., 2024).



The EHDS's secondary-use provisions also do not stand alone; they must be reconciled with the pre-existing General Data Protection Regulation (GDPR), and comparative legal analysis of GDPR-based secondary use of health data across member states finds substantial divergence in how national data protection authorities interpret key GDPR provisions relevant to health research and analytics, including the scope of the public-interest and scientific-research legal bases and the conditions under which pseudonymised health data may be shared across institutional and, by extension, national boundaries [12]. This divergence matters directly for digital health applications that depend on aggregated or federated data to function — for instance, adaptive digital therapeutics or AI-assisted diagnostic software trained or continuously updated on multi-country data — because the same product may face materially different data-access conditions depending on the member state in which its data controller is established. Emerging work on dynamic consent mechanisms under EU law proposes that machine-readable, granular consent management could partially reconcile the GDPR's patient-centred consent requirements with the EHDS's ambition for broader secondary-use data flows, but finds that no member state has yet operationalised such a mechanism at a scale sufficient to demonstrate it resolves the tension rather than merely relocating it to a technical layer [18]. Finally, where digital health data or the digital health applications processing it are handled by providers or research partners outside the European Economic Area, cross-border transfer rules add a further, EU-external harmonisation problem: analysis of continuing EU-US health data transfer friction finds that even after the adoption of the EU-U.S. Data Privacy Framework, health research collaborations involving data transfer to the United States continue to face case-by-case adequacy and safeguard requirements that are applied inconsistently across member state supervisory authorities, adding a layer of jurisdictional variability on top of the EHDS's internal harmonisation project [19]. Figure 1 illustrates the number of distinct national or EU-level instruments that a digital health application must typically satisfy to achieve full market access, reimbursement, and cross-border data interoperability, and Figure 2 summarises the comparative maturity of harmonisation across the three domains reviewed.

Discussion

Three broad conclusions follow from synthesising this literature. First, the European Union's harmonisation achievement is real but domain-specific: the MDR provides a genuinely uniform legal classification and market-access standard for digital health applications, and the AI Act is extending a comparably uniform (if not yet fully reconciled) standard to AI-enabled products, but this device-level harmonisation does not extend to reimbursement, which remains governed by four structurally distinct national logics even among the four systems compared here [5,8,3]. A manufacturer can therefore achieve EU-wide market access through a single CE mark while still needing to construct separate, non-transferable evidence packages for German, French, Belgian, and other national reimbursement bodies — a bifurcation that the comparative HTA literature identifies as the principal source of duplicated cost and delayed patient access in this sector [7,16].

Second, even within domains formally designated for harmonisation, implementation capacity is a second, largely independent axis of variation from the legal text itself. The MDR's notified body bottleneck and the EHDS's uneven technical readiness for federated secondary-use analytics both illustrate that passing a harmonising regulation is necessary but not sufficient; without commensurate investment in institutional and technical capacity distributed evenly across member states, formally uniform rules can still produce unevenly realised outcomes in practice [6,10]. This suggests that future EU harmonisation efforts in this space should be evaluated not only on the uniformity of the legal instrument itself but on parallel, comparable investment in the notified bodies, health data access bodies, and national HTA agencies tasked with operationalising it.

Third, the reimbursement fragmentation identified here is not obviously a policy failure so much as an unresolved trade-off between subsidiarity in health system financing — a core competence member states have historically guarded closely — and the efficiency gains a more harmonised digital health evidence standard could offer manufacturers and, ultimately, patients awaiting access. The mutual-learning dynamic documented among German, French, Belgian, and UK HTA bodies suggests that convergence, where it occurs, is more likely to happen informally, through shared terminology and cross-referenced evidentiary frameworks, than through a binding EU reimbursement directive that would require member states to cede financing authority they are unlikely to relinquish in the near term [7].

This review has several limitations. As a narrative rather than systematic review, the literature search, while targeted and individually verified for each included source, may not capture the full universe of national-language policy analyses, particularly non-English-language legal and health-services scholarship on smaller member states' digital health reimbursement schemes. The comparative country set here — Germany, France, Belgium, and the United Kingdom — reflects where the comparative HTA literature is most developed, and conclusions about the pace of EU-wide reimbursement convergence should be read as most confidently applicable to these systems rather than generalised uniformly across all twenty-seven member states. Finally, because the EHDS is still in its early implementation phase and the AI Act's

medical-device-relevant guidance continues to be issued, some conclusions drawn here about interoperability and AI/MDR reconciliation may understate harmonisation gains realised after the sources reviewed were published.

Conclusion

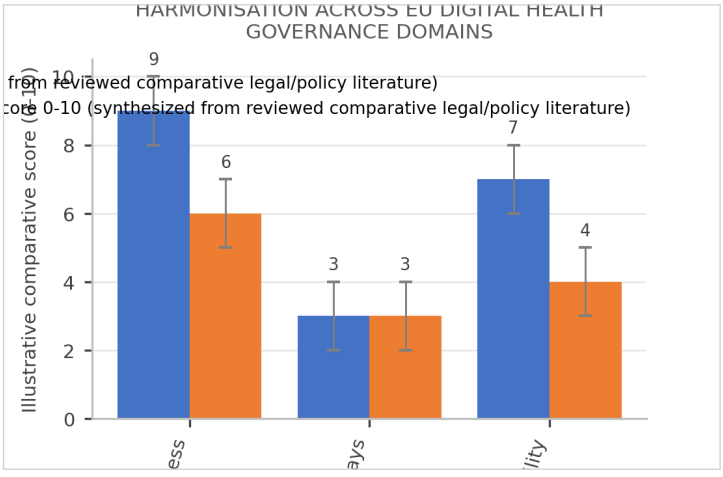
Regulatory harmonisation of digital health applications across the European Union has proceeded furthest where the Union holds direct, exclusive competence — device classification and market access under the MDR, now extending to AI-enabled products under the AI Act — and least far where reimbursement decisions remain a jealously guarded national competence, producing at least four structurally distinct evidentiary and financing pathways among the systems compared in this review. The European Health Data Space represents the most ambitious current attempt to harmonise a third domain, cross-border data interoperability, but its legal ambition currently runs ahead of the technical and institutional capacity needed to realise it uniformly across member states. For manufacturers, health systems, and patients, the practical consequence of this uneven harmonisation is that a single CE-marked digital health application can be simultaneously "harmonised" for market entry and functionally fragmented for reimbursement and cross-border data use — a distinction policymakers evaluating the EU's digital health regulatory architecture should treat as three separate harmonisation projects, each requiring its own benchmark for success, rather than a single undifferentiated goal.

References

1. Schmidt L, Pawlitzki M, Renard BY, Meuth SG, Masanneck L (2024) The three-year evolution of Germany's Digital Therapeutics reimbursement program and its path forward. npj Digital Medicine, 7(1):139, DOI:10.1038/s41746-024-01137-1.

2. Mäder M, Timpel P, Schönfelder T, Militzer-Horstmann C, Scheibe S, Heinrich R, Häckl D (2023) Evidence requirements of permanently listed digital health applications (DiGA) and their implementation in the German DiGA directory: an analysis. BMC Health Services Research, 23(1):369, DOI:10.1186/s12913-023-09287-w.

Illustrative comparative maturity of regulatory harmonisation across three domains of EU digital health governance: device classification and market access, national reimbursement/HTA, and cross-border data interoperability, synthesized from the comparative legal and policy literature reviewed (Francesconi et al., 2025; Tarricone et al., 2024; Hussein et al., 2025).



3. Lievevrouw E, Marelli L, Van Hoyweghen I (2024) Weaving EU digital health policy into national healthcare practices. The making of a reimbursement standard for digital health technologies in Belgium. Social Science & Medicine, 346:116620, DOI:10.1016/j.socscimed.2024.116620.

4. Unsworth H, Dillon B, Collinson L, Powell H, Salmon M, Oladapo T, Ayiku L, Shield G, Holden J, Patel N, Campbell M, Greaves F, Joshi I, Powell J, Tonnel A (2021) The NICE Evidence Standards Framework for digital health and care technologies - Developing and maintaining an innovative evidence framework with global impact. DIGITAL HEALTH, 7:20552076211018617, DOI:10.1177/20552076211018617.

5. Francesconi M, Cangi M, Tamarri S, Conditi N, Menicucci C, Ravizza A, Cattaneo L, Bianchini E (2025) Navigating regulatory challenges across the life cycle of a SaMD. Journal of Biomedical Informatics, 167:104856, DOI:10.1016/j.jbi.2025.104856.

6. Svempe L (2026) Impact of the new European medical device regulation on digital health manufacturers. npj Digital Medicine, 9(1):638, DOI:10.1038/s41746-026-02812-1.

7. Tarricone R, Petracca F, Weller HM (2024) Towards harmonizing assessment and reimbursement of digital medical devices in the EU through mutual learning. npj Digital Medicine, 7(1):268, DOI:10.1038/s41746-024-01263-w.

8. Arcà E, Heldt D, Smith M (2025) Comparison of health technology assessments for digital therapeutics in Germany, the United Kingdom and France. DIGITAL HEALTH, 11:20552076241308704, DOI:10.1177/20552076241308704.

9. Hussein R, Gyrard A, Abedian S, Gribbon P, Alabart Martinez S (2025) Interoperability Framework of the European Health Data Space for the Secondary Use of Data: Interactive European Interoperability Framework-Based Standards Compliance Toolkit for AI-Driven Projects. Journal of Medical Internet Research, 27:e69813, DOI:10.2196/69813.

10. van Drumpt S, Chawla K, Barbereau T, Spagnuelo D, van de Burgwal L (2025) Secondary use under the European Health Data Space: setting the scene and towards a research agenda on privacy-enhancing technologies. Frontiers in Digital Health, 7:1602101, DOI:10.3389/fdgth.2025.1602101.

11. Carradinha M, Mendes VIS, Moura RP, Silva NP, Rocha L, Gonçalves J, Antunes I, Schiza E, Pattichis CS, Zanini A, Pajić V, Pinto CS (2026) Telemedicine and the European Health Data Space: a new paradigm for healthcare in the EU. Frontiers in Digital Health, 7:1713758, DOI:10.3389/fdgth.2025.1713758.

12. Vukovic J, Ivankovic D, Habl C, Dimnjakovic J (2022) Enablers and barriers to the secondary use of health data in Europe: general data protection regulation perspective. Archives of Public Health, 80(1):115, DOI:10.1186/s13690-022-00866-7.

13. Aboy M, Minssen T, Vayena E (2024) Navigating the EU AI Act: implications for regulated digital medical products. npj Digital Medicine, 7(1):237, DOI:10.1038/s41746-024-01232-3.

14. Schmidt J, Schutte NM, Buttigieg S, Novillo-Ortiz D, Sutherland E, Anderson M, de Witte B, Peolsson M, Unim B, Pavlova M, Stern AD, Mossialos E, van Kessel R (2024) Mapping the regulatory landscape for artificial intelligence in health within the European Union. npj Digital Medicine, 7(1):229, DOI:10.1038/s41746-024-01221-6.

15. Sippli K, Deckert S, Schmitt J, Scheibe M (2025) Healthcare effects and evidence robustness of reimbursable digital health applications in Germany: a systematic review. npj Digital Medicine, 8(1):495, DOI:10.1038/s41746-025-01879-6.

16. Liang J, Fang Q, Jiao X, Xiang P, Ma J, Zhang Z, Liu Y, He Y, Li Y, He Z, Lei J (2025) Approved trends and product characteristics of digital therapeutics in four countries. npj Digital Medicine, 8(1):308, DOI:10.1038/s41746-025-01660-9.

17. Fassbender A, Donde S, Silva M, Friganovic A, Stievano A, Costa E, Winders T, van Vugt J (2024) Adoption of Digital Therapeutics in Europe. Therapeutics and Clinical Risk Management, 20:939-954, DOI:10.2147/TCRM.S489873.

18. Phuyal S, Bhandari M, Correia Bezerra R, Bista R, Ferreira JC (2026) Dynamic Consent for Secondary Use of Health Data: Challenges and Opportunities Under European Law. JMIR Medical Informatics, 14(1):e93348, DOI:10.2196/93348.

19. Lalova-Spinks T, Valcke P, Ioannidis JPA, Huys I (2024) EU-US data transfers: an enduring challenge for health research collaborations. npj Digital Medicine, 7(1):215, DOI:10.1038/s41746-024-01205-6.