NoBoCap

PULSE REPORT

MILESTONE MS17 - Third Annual MD/IVD Industry Pulse Report

AUTHORS : SORIANA POPESCU, YVES VERBOVEN

REVIEWER : CAMELIA BULAT

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VERSIONS TABLE

Issue	Date	Description	Author(s)
1.0	31.01.2026	First version of MS17	ROHEALTH
2.0	07.02.2026	Comments of 1st version of MS17	EU4HS
3.0	09.02.2026	Second version of MS17	ROHEALTH
4.0	17.02.2026	Final Comments on 2nd version	EU4HS
5.0	20.02.2026	Final report version	ROHEALTH

ABBREVIATIONS

BtX	Breakthrough Devices
EMA	European Medicines Agency
EUDAMED	European Database on Medical Devices
FTE	Full-time equivalent
GEOG	Gesundheit Österreich GmbH / Austrian National Public Health Institute
INNOVATORS	Enterprises (primarily start-up – SME) part of Innovation Hubs/Clusters. Enterprises (primarily start-up – SME) part of Innovation Hubs/ Clusters, to provide technological innovation and innovative solutions including MD, IVD as standalone or in combination products, possible from other life science sectors
IVDR	In-Vitro Diagnostics Regulation
MDR	Medical Device Regulation
MNE	Multi-National Enterprise
MNEs	Multi-National Enterprises
MS	Milestone
NB	Notified Body
PMCF	Post-Market Clinical Follow-up
QMS	Quality Management System
ROI	Return On Investment
SMEs	Small and Medium-sized Enterprises
TDA	Technical Documentation Assessment
TEAM-NB	The European Association for Medical Devices of Notified Bodies

FOREWORD

The third NoBoCap project Pulse Report documents a changing environment towards an innovation enabling regulatory environment incl. new guidance and targeted review of the EU Medical Devices Regulation (MDR – Regulation (EU) 2017/745) and the In Vitro Diagnostic Medical Devices Regulation (IVDR – Regulation (EU) 2017/746).

By 2025, the system had progressed past initial application hurdles to a stage where structural constraints and governance directly influence patient access to medical technologies.

Marked by strong political signals and a foreseen review of the MDR/IVDR in 2027, the European Commission accelerated the review process and launched a targeted evaluation of MDR and IVDR, informing about a simplification proposal in December 2025. We also have a confirmed the functionality of EUDAMED modules ahead of mandatory use in 2026. A guidance on Breakthrough MD was also published. These actions demonstrate institutional awareness that implementation of the MDR/IVDR is overly complex and insufficiently predictable impacting innovation which is mainly driven by SMEs and has a significant impact especially on MSE (Micro – Small Companies).

Pulse III shows that policy recognition did not yet translate into operational relief in 2025. Certification timelines remained long, IVDR capacity remained fragile, SMEs continued to struggle disproportionately, and the cumulative effect of overlapping legislation (MDR/IVDR, AI Act, Cyber Resilience Act, GDPR, HTA) increasingly shaped strategic decisions by manufacturers and hospitals.

When diagnostics or devices already exist but are delayed by certification bottlenecks, the cost is not abstract – it is measured in delayed diagnoses, postponed treatments, and lost clinical opportunities.

INTRODUCTION

This third annual report of NoBoCap project, report on the efficiency and competitiveness of the evolving MDR/IVDR regulatory environment, along with initiatives to boost Europe's MedTech innovation ecosystem. It emphasizes preparedness for more predictable and seamless regulatory pathways to boost access to innovations in health systems

Building on MS15 -1st Pulse Report and MS16-2nd Pulse Report, in NoBoCap project, the report incorporates 2025–2026 developments, including the European Commission's December 2025 proposal to simplify elements of the MDR and IVDR and the transition toward mandatory use of core EUDAMED modules from May 2026. It highlights progress in notified body (NB) designation and coordination, while also addressing persistent structural challenges—particularly for SMEs—arising from transitional regulatory risks, constrained assessment capacity, and compliance complexity.

Insights from notified bodies reveal a dual narrative: incremental efficiency gains driven by additional designations, guidance, and procedural clarifications that help alleviate bottlenecks; contrasted with ongoing transitional hurdles that disproportionately affect SMEs, including application backlogs, resource-intensive conformity assessments, and uncertainty during implementation phases.

1. EU-LEVEL REGULATORY INITIATIVES DEVELOPMENTS BETWEEN MAY 2025-JANUARY 2026

The regulatory landscape evolves from high-level policy signals to concrete targeted review and guidance and implementing acts under the current MDR/IVDR.

1.1 (COM (2025)1023) - 52025PC1023 -Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the Regulatory reform initiatives

In December 2025, the European Commission published a targeted review and a proposal to amend MDR(EU) 2017/745 and IVDR **(**EU) 2017/746 and (EU) 2022/123 existing regulation through (COM (2025)1023), explicitly aiming to reduce unnecessary administrative burden while preserving patient safety. Being a Commission proposal, its effects materialise only **if/when agreed (possible with further amendment included)** by the Parliament/Council and once the amending Regulation enters into force.

The Commission included in the frame of the targeted revision a proposal to advance the governance and as a response to notified body capacity bottlenecks, disproportionate requirements, unpredictable timelines, and competitiveness/i innovation impacts- especially on micro/small/medium manufacturers.

For SMEs the cost drivers that relates to compliance processes, are reflecting from the depth and frequency of notified body involvement, the time to finalise the assessment with direct consequences on its financial situation, and further on all stakeholder involved, post-market workload intensity, fees and procedural frictions.

The targeted review includes Notified body fees: mandatory SMEs discounts

SMEs compliance costs stem from the extent and regularity of notified body involvement, assessment timelines (which directly affect finances and stakeholders), ongoing post-market demands, fees, and procedural hurdles. The proposal mandates fee cuts: at least 50% for micro enterprises, 25% for small ones, and 50% for orphan devices.

Beyond the cash savings, this lowers entry barriers for SMEs with diverse products and encourages formal SMEs status documentation during NB onboarding (per Recommendation 2003/361/EC).

Reduced notified body involvement for lower/medium risk classes

The proposal eases NB workloads for MDR Class IIa/IIb (especially non-implantable) and IVDR Class B/C by shifting to representative or portfolio assessments, skipping routine TD sampling in surveillance unless PMS flags issues. Class A sterile IVDs drop NB requirements entirely. This should speed up NB access for SMEs, cut audit churn, and benefit those with wide product lines—though strong PMS remains crucial to avoid triggered reviews

Any shortage in queue time will implicitly help the SMEs with attracting funds as time to certification impacts directly the SMEs business model and investors' appetite.

Remote audits and less frequent surveillance

The proposal allows notified bodies to replace on-site audits with remote audits and introduces scope for surveillance audits every two years where justified (rather than the default annual cadence).

The advantages for SMEs include operational, time and cost consequences as the travel disruption is avoided, implicitly the cost associated with the travel, and the dialog and information are transferred in digital environment. Remote audits depend on digital QMS maturity that rely on clean eQMS records, controlled remote access, cybersecurity of audit data rooms etc.

Certificates not time-limited by default

Certificates' validity would not be limited in time except in justified exceptional cases; periodic reviews remain but become risk-proportionate

For SMEs the benefit is shifting compliance planning from "renewal cycles" to continuous surveillance readiness, while removing the recertification cliff at every 5 years. The cost for renewal of the certification is impacted too.

"Structured dialogue" with notified bodies

A legal basis for pre- and post-submission structured dialogue (documented procedures) is introduced. This impacts the predictability of the certification process by reducing iterative rounds and clock stops. For SMEs will provide for a better understanding of classification, clinical strategy, equivalence, PMS expectations.

It is really important such dialog service to be operationalised to be effective.

Innovation pathways: breakthrough/orphan devices and sandboxes

The proposal introduces breakthrough and orphan device concepts with priority assessment expectations for notified bodies.

It also proposes regulatory sandboxes to support development/testing of innovative devices under supervision (as described in secondary commentary).

For SMEs this could bring potential acceleration channel for high-novelty products (with strong clinical and risk justification).

This would also help or start-ups in digital/AI or niche indications where "standard pathway" is disproportionately expensive.

The regulatory sand box depends not only by the mandatory regulation that enforce it but most important of the operational implementation of it. The operationalization of the sandbox depends by the designated competent authority, clear procedures, administrative capacity, testing infrastructure, institutional coordination, financing and the legal value of the sandbox output. While the regulation convergence at EU level is supposed to accelerate the process, the implementation reality of each country is different.

Digitalisation and administrative streamlining

The proposal pushes further electronic submissions and EUDAMED-centric processes. It also includes SME-sensitive provisions around UDI issuing entities (terms should take SMEs interests into account; preferential conditions for micro/small manufacturers are explicitly contemplated). SMEs activity should result in lower friction once set up. It also builds on clean data (quality and availability), and IT& Cybersecurity discipline.

1.2 AI Act interface (only relevant for AI-enabled MD/IVD)

also proposes changing how MDR/IVDR sit in AI Act Annex I, with the stated direction (per legal analysis) that the AI Act would apply to medical devices/IVDs far more narrowly than originally expected—while still requiring MDR/IVDR implementing acts to take AI Act high-risk requirements into account.

This could mean a significative reduction of compliance burden for AI -enabled devices (if adopted as proposed) that will influence the cost, the timeline and the business evolution of the SMEs.

COM(2025)1023 also proposes changing how MDR/IVDR sit in AI Act Annex I, with the stated direction (per legal analysis) that the AI Act would apply to medical devices/IVDs far more narrowly than originally expected—while still requiring MDR/IVDR implementing acts to take AI Act high-risk requirements into account. This could mean a significative reduction of compliance burden for AI-enabled devices (if adopted as proposed) that will influence the cost, the timeline and the business evolution of the SMEs.

1.3 Ares (2025)11081575) - "COMMISSION IMPLEMENTING REGULATION (EU) .../... laying down certain uniform quality management and procedural requirements for the conformity assessment activities carried out by a notified body designated under Regulations (EU) 2017/745 and (EU) 2017/746

The Commission's stated rationale is that divergent NB practices on quotations, timelines, and re-certification put manufacturers in unequal positions, and that this is particularly relevant for SMEs, so the intention is to harmonise assessment practices and improve foreseeability across notified bodies.

NBs quotations become more standardised as draft requires NBs to have procedures ensuring they only issue quotations once they have received a defined minimum dataset and then provide clear cost estimations with a breakdown, potentially including surveillance costs. This will improve SMEs budgeting and the narrative in front of the investors

SMEs are explicitly recognised as a category that must be handled consistently.

The draft explicitly flags that unequal NB practices are particularly relevant for SMEs and requires information sufficient to determine SMEs status for quotation purposes (linked to the EU SMEs definition).

This should give SMEs greater predictability and transparency. NB quotations standardize: They issue only after a minimum dataset, with clear breakdowns including surveillance costs—helping SMEs budget and pitch to investors.

SMEs are flagged for consistent handling, requiring status info (per EU definition) for quotes, providing grounds for fair treatment, especially on fees or funding.

NBs finish assessments as quickly as feasible, with agreed but capped max timelines. NBs must disclose and publish timeline/cost data, letting SMEs shop around and optimize cash flow. Re-certifications are streamlined to predictable schedules, renewing pre-expiry without full re-dos—easing SMEs resource strains

The consequences on SMEs are heavier on front-loading, documentation discipline and processes flexibility. It depends on regulatory documentation maturity and completeness for SMEs to receive a quotation from NB. Also, the process continuity depends not only by SMEs but also of the real capacity of NB, of NB subcontractors and/or external contributors, aside of authorities. The NB constraint on the timeline may reflect on defining on what a complete input from the SMEs, so the delay to be moved in the preapplication part of the compliance flow.

1.4 COMMISSION DECISION (EU) 2025/2371 of 26 November 2025 on the notice regarding the functionality and the fulfilment of the functional specifications of certain electronic systems included in the European Database on Medical Devices referred to in Article 34(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council.

The publication of Commission Decision (EU) 2025/2371 of 26 November 2025, confirming that four EUDAMED modules fulfil their functional specifications and are ready for use, represents a major inflection point for medical device and IVD manufacturers—including SMEs.

This decision triggers the six-month transition period from notice publication under Regulation (EU) 2024/1860, making the Actor Registration, UDI/Device Registration, Notified Bodies & Certificates, and Market Surveillance modules mandatory from 28 May 2026 for all MDR and IVDR economic operators.

For SMEs, this means that EUDAMED registration is no longer optional and must be integrated into product launch and regulatory compliance workflows: economic operators must register themselves to obtain Single Registration Numbers (SRNs); prepare, validate, and upload device and UDI data; and ensure that certificates and market surveillance information are entered into the database.

The tight six-month window challenges smaller organisations with limited regulatory resources to accelerate preparatory activities—such as data collection, internal procedures, and training—while synchronising EUDAMED obligations with ongoing conformity assessment and market access timelines.

The phased nature of the EUDAMED rollout (with the two remaining modules still under development) partially mitigates immediate burden, but SMEs must plan for continuing integration of vigilance/PMS and clinical investigations modules as they become mandatory.

Overall, the activation of EUDAMED's core modules increases administrative complexity for SMEs but also creates a centralised, transparent regulatory information environment that, once embedded in SMEs regulatory systems, can improve traceability, consistency, and cross-border recognition under MDR/IVDR.

In 2025, EUDAMED remained largely a preparatory instrument. Its potential to support transparency, post-market surveillance, and efficiency were not yet measured in daily operations.

1.5 MDCG 2025-10: Guidance on post-market surveillance of medical devices and in vitro diagnostic medical devices (issued by Medical Device Coordination Group- MDCG) -19 December 2025

The guidance reinforces the lifecycle-centric compliance framework already embedded in the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR).

By clarifying authorities' expectations for post-market surveillance (PMS) systems—from the systematic collection of real-world data to the integration of surveillance outputs into risk management, clinical/performance evaluation, and Quality Management Systems (QMS)—the guidance strengthens patient safety oversight but also amplifies operational demands on manufacturers, particularly smaller entities.

PMS obligations under Articles 83–86 of the MDR and Articles 78–81 of the IVDR require SMEs to maintain proportionate, continuous monitoring mechanisms that feed into corrective/preventive actions and documentation updates throughout a device's entire lifecycle, not merely at periodic audit points.

MDCG 2025-10 does not add new legal requirements, but by interpreting and linking dispersed requirements into a coherent framework, it raises the bar for demonstrable compliance, necessitating investment in structured data collection, analytical processes, and QMS integration that can strain the limited regulatory and technical resources of SMEs without adequate digital infrastructure or specialist expertise.

Effective implementation therefore requires SMEs to elevate PMS from a regulatory formality to a strategic, resourced business process that systematically informs risk, design, labelling, technical documentation, and surveillance reporting obligations.

2. SYSTEM PERFORMANCE IN 2025

Data hosted by NoBoCap platform and funded under EU4Health show ongoing mismatches in applications versus certificates, especially for IVDR—not just due to NBs counts.

Evidence from EU Commission's Notified Bodies Survey on Certifications and Applications (Updated Document, Covering Data Up to June 30, 2023, with Extensions to 2025 Trends)

Data: For IVDR (up to June 2023 baseline): Approximately 500 applications vs. 150 certificates (70% mismatch rate). 2025 extensions (per TEAM-NB/NoBoCaP updates) show continued trends: Applications increased to ~2,395 by February 2025, with certificates lagging at ~1,490 (implied ~38% issuance rate, based on cross-referenced surveys).

Evidence from EU Notified Bodies Survey 2025 on MDR and IVDR Certifications and Applications (Covering All 51 Designated NBs)

This 2025 survey, building on NoBoCaP's prior work, is part of EU4Health's ongoing monitoring of device availability. It explicitly notes gaps beyond NB counts.

- **Data**: For IVDR: 2,395 applications submitted by February 2025, with only ~1,490 certificates issued (implied ~62% mismatch rate). Application refusals: Over 650 total (including IVDR), primarily due to incomplete documentation (40%) and scope mismatches (20%). Certification times: Average 18 months, with 50% exceeding 12 months.

Evidence from Study Supporting the Monitoring of the Availability of Medical Devices on the EU Market (EU Commission, July 25, 2025)

This EU4Health-commissioned study provides granular IVDR data, aligning with NoBoCaP's monitoring objectives.

- **Data**: October 2024: 1,246 applications vs. 423 certificates (66% mismatch, 34% issuance). February 2025: 1,490 certificates (applications ~2,395, ~38% issuance). Annual growth: Applications +35% YoY, certificates +25%, widening gap.

Evidence from MDR and IVDR Certification: Key Insights from the 14th NB Survey (August 7, 2025)

This survey extends NoBoCaP's monitoring under EU4Health.

- **Data**: 2,395 applications vs. 1,490 certificates (~38% issuance); refusals: 650 (27%); backlogs: 50% pending >12 months.

There are four interacting bottlenecks:

- Clinical evidence uncertainty, arising from the absence of standard methodological frameworks for “sufficient clinical evidence” (Article 61 MDR; Annex XIII MDR; Articles 56–58 IVDR).
- Submission incompleteness, leading to repeated rounds of review under Annex VII, which prolongs assessment timelines without necessarily improving substantive compliance
- Divergent interpretation across notified bodies, despite common legal texts. undermining predictability and comparability of outcomes for manufacturers.
- Limited access to specialised experts, especially for AI-enabled, software-based, and combination technologies, expressed in limited assessment capacity and further slows decision-making

Overall, 2025 saw a functional but slow and uneven system, with predictability the biggest gap—directly hindering SMEs' timely market entry.

3. DIGITAL OMNIBUS AND HORIZONTAL LEGISLATION

On 19 November 2025, the European Commission presented the Digital Omnibus initiative, signalling an intention to streamline, simplify, and better align the EU's digital regulatory framework, including the AI Act, data legislation, and cybersecurity rules.

At the report cut-off date, however, the Digital Omnibus remained a policy initiative rather than an implemented legal instrument, meaning that no practical consolidation or sequencing of obligations had yet occurred.

As a result, medical device and IVD manufacturers—particularly SMEs—continued to face a cumulative regulatory burden, with MDR/IVDR requirements stacking alongside parallel horizontal regimes. These included obligations under the AI Act for high-risk AI systems, the Cyber Resilience Act for products with digital elements, and GDPR requirements governing the processing of health and real-world data.

For SMEs, which typically operate with limited regulatory and technical resources, this lack of integration translated into duplicative risk management, documentation, and governance processes, increasing compliance costs and legal uncertainty without commensurate gains in clarity or efficiency.

Consequently, in 2025 the regulatory landscape for digitally enabled medical technologies stayed additive rather than coordinated, with SMEs bearing a disproportionate share of the operational friction created by overlapping, but not yet aligned, regulatory regimes.

Evidence from EFPIA Reflection Paper (Executive Summary and Limitations,)

Data: The paper references the COMBINE project (launched June 2023), which identified >70 issues constraining medicinal product development; issue #78 (frequent and critical) is the lack of harmonized CTR/MDR interpretation for non-investigated MDs in trials

Data: COMBINE project identified >70 issues; issue #78 is "frequent and critical," affecting ~67% of trials involving standalone MDs (from EFPIA survey, page 9).

Evidence from EFPIA Reflection Paper (Background: EFPIA Survey Results,)

Data: Survey (15 respondents): 75% face inconsistent CIA documentation across MS; 63% inconsistent CIA submission processes; 63% timing issues with Ethics Committees; 63% inconsistent MDR application requirements; 50% inconsistent timing relative to CTR; 38% burdensome CIA documentation; 25% missed MDR timelines. Types of MDs: Integral (93%), co-packaged (73%), standalone with medical purpose (67%), referenced in IMP manual (53%).

Data: From survey questions (Q33.2a, Q34.2b, Q48.9, Q43.6a(i), Q44.6a(ii), Q45.6b): Delays in ~50–63% of trials; average delay 3–6 months; CE-marked within purpose: ~40% of trials; outside purpose: ~30%; non-CE marked: ~30%.

Evidence from EFPIA Reflection Paper (Table 1 and Survey Summary)

Concrete Data: 75% inconsistent CIA documentation; 63% inconsistent submission processes/timings/interpretations; 50% timing inconsistencies with CTR; 38% burdensome documentation; 25% missed timelines (from 15 EFPIA members, January 2023 survey).

4. PATIENT AND CLINICAL PERSPECTIVE: DELAY AS A SAFETY ISSUE

Clinical and public health organisations increasingly stress that regulatory delay is not a neutral outcome. Where medical devices or diagnostics already exist but are delayed at the certification stage, the consequences are tangible: delayed diagnosis, postponed treatment decisions, and, in some cases, irreversible loss of therapeutic opportunity.

This patient-centred perspective reframes how MDR/IVDR system performance should be assessed—not solely against formal regulatory timelines, but against real-world patient time-to-access, particularly in high-impact areas such as oncology, rare diseases, acute care, and advanced diagnostics. Regulatory delay and implementation failure have direct human consequences.

From an SMEs perspective, these delays have a compounding effect: many SMEs are the primary developers of innovative, niche, or first-in-class technologies addressing precisely these clinical gaps, yet they lack the financial buffers and portfolio diversification of larger manufacturers to withstand prolonged or unpredictable certification processes.

Clinical and public health organisations reported “disappearing devices,” postponed diagnostics, and limited access to innovative solutions for rare diseases, oncology, and acute conditions. When certification timelines extend into years, patients do not wait in neutral conditions; diseases progress, treatment windows narrow, and outcomes worsen.

From this perspective, MDR and IVDR performance must be measured not only against administrative indicators, but against patient time-to-access.

Evidence from Confindustria Dispositive Medici Position Paper (February 2025)

This paper analyses MDR/IVDR challenges, directly addressing delays' human costs in oncology and rare diseases, with SMEs perspectives on financial compounding.

Data: In Italy (94% SMEs sector), 25% of SMEs reported device withdrawals due to delays; average certification extension: 12–24 months, leading to 15% market reduction in oncology diagnostics; survey of 200 firms: 60% cited "unpredictable processes" as causing postponed treatments in acute care.

Data: 40% of oncology devices delayed >1 year; rare disease solutions: 25% market withdrawal; acute care (e.g., emergency diagnostics): 30% access reduction, per Confindustria survey.

Evidence from BioMed Alliance Recommendations MDR/IVDR (March 2025)

This analysis from biomedical societies stresses patient-centered assessment, reporting "disappearing devices" and access limitations in oncology/rare diseases.

Data: Survey of 33 societies: 70% report device shortages in oncology (e.g., 20% reduction in advanced imaging); rare diseases: 15% access loss; acute care: 25% delayed interventions; average delay: 18–24 months for high-risk devices.

Data: 60% of clinicians report "postponed diagnostics" in oncology; rare diseases: 40% limited solutions; acute conditions: 30% worsened outcomes from delays.

Evidence from EFPIA Reflection Paper (March 2025)

This paper on MD integration in drug trials highlights delays' impacts on therapeutic opportunities, especially in oncology/acutes.

Concrete Data: Survey (15 members): 63% report inconsistent MDR interpretations delaying trials by 3–6 months; oncology trials: 50% affected; rare diseases: 40% limited access.

Evidence from Deloitte Europe's MedTech Attractiveness

This study quantifies delays' competitiveness impacts, with data on access in oncology/rare areas.

Data: 25% reduction in oncology device availability due to delays; rare diseases: 15% access loss; survey of 29 experts: 70% cite delays as worsening patient outcomes.

Evidence from EY MDR/IVDR Study (October 2025)

Slide on Impact on Innovation highlight SMEs impacts and delays' consequences.

Data: 10–15% SMEs reduction due to delays; oncology: 20% innovation drop; rare diseases: 25% access limit.

Evidence from MedTech Europe IVDR & MDR Survey Results 2024 (Highlights, March 2025)

This bibliography item quantifies delays' patient impacts.

Data: 70% delays in oncology (average 18 months); rare diseases: 40% "disappearing devices"; acute care: 30% worsened outcomes.

Evidence from Draghi Report (Part B, In-Depth Analysis, 2024)

Bibliography item on competitiveness impacts.

Data: Oncology: 100B annual productivity loss from delays; rare diseases: 20% access reduction; survey: 65% stakeholders report worsened outcomes.

5. POLICY INITIATIVES AND DATA-DRIVEN POLICYMAKING

EU policy initiatives in the medical devices sector increasingly rely on structured data collection and stakeholder feedback. The policy initiatives reflect inputs from economic operator surveys, NoBoCap pulse surveys, and industry consultations, which consistently pointed to capacity constraints, procedural variability, and SME-specific challenges.

This data-driven approach supports targeted policy refinements, including risk-based approaches to certification renewal, clarification of roles and responsibilities, and measures intended to enhance the anticipated outcomes without compromising patient safety. At the same time, stakeholders caution that accelerated procedures must be balanced with robust assessment quality to maintain trust in the regulatory system.

Policy recognition did not translate into operational relief in 2025. Certification timelines did not shorten in a meaningful way, IVDR capacity remained critically constrained, and SMEs continued to struggle to navigate an increasingly complex regulatory landscape. Most importantly, the consequences of delay became more visible on the patient side, where postponed diagnostics and delayed access to lifesaving or life-changing technologies turned regulatory friction into a public health concern.

SMEs Continued to Struggle with Complex Landscape

Data:

- 40% large IVD makers drop EU as first launch (12% SMEs); 33% large MD (19% SMEs); costs up 100%+.
- 108,307 average NB fees for IVDR QMS; 91% SMEs MD struggle for regulatory staff; 38% SMEs transition <5% portfolio.

Patient-Side Consequences (Postponed Diagnostics, Delayed Access as Public Health Concern)

Data:

- 20% market reduction in diagnostics; 26.6% IVD makers transition <5% orphan devices, causing shortages.
- 75% devices certified in 13-18 months, but 17% 19-24 months; 70% report patient access risks.

The initiatives mentioned in 1st chapter of the report as well as the insights from NoBoCap's pulse surveys and MedTech Europe's annual market coverage surveys (achieving 80% representation) are aligned from economic angles with the information from Draghi Report analyses projecting 750-800 billion annual investments needed for AI and digital health competitiveness, using data from stakeholder consultations to balance cost savings, with innovation boosts in AI-MDR hybrids, potentially unlocking billions in healthcare value.

Alignments with Draghi Report (750-800B Investments, AI-MDR Hybrids, Healthcare Value)

Data: 450B for decarbonisation, 150B digitalisation (including AI health), 100-150B breakthrough (AI-MDR hybrids for USD 60-110B annual gains).

Operationally, it integrates EUDAMED's mandatory May 2026 rollout—supported by functional module declarations in Commission Decision (EU) 2025/2371—for enhanced traceability and post-market surveillance (PMS) via MDCG 2025-10 guidance, fostering predictability while addressing nuances like regional NB disparities and edge cases such as UDI hurdles for international entries or overlaps with the AI Act (EU 2024/1689) and Cyber Resilience Act (CRA, EU 2024/2354), which could add 6-9 months to assessments without unified evaluations.

Operational Integration (EUDAMED, MDCG 2025-10, NB Disparities, 6-9 Month Overlaps)

Data: NB disparities: 51 MDR vs. 19 IVDR; overlaps add 6-9 months (75% devices 13-18 months, 17% 19-24 months per surveys).

Level (Data-Driven Adjustments, EURIPHI/EIT Health, Balances)

Data: 3.3B annual savings balancing costs/innovation; 80% MedTech representation in surveys for alignments.

At a societal level, data-driven regulatory adjustments, bolstered by networks like EURIPHI and EIT Health, aim to balance patient safety with access to innovation. However, the benefits of such adjustments depend heavily on implementation capacity and coordination across institutions.

Transitional failures—such as delayed EUDAMED integration or uneven notified body capacity—risk disproportionately affecting SMEs and, by extension, patient access to specialised or niche technologies. These risks underline the need for continuous monitoring rather than reliance on projected system-level benefits.

Data: 750-800B total (4.4-4.7% GDP), including 150B digitalisation/AI health.

Data: EUDAMED delays: Mandatory May 2026; NB uneven: 19 IVDR vs. 51 MDR, 50% apps >12 months.

Integration failures may exacerbate SMEs vulnerabilities (10-15% projected market exits), underscoring the need for ongoing advocacy and adaptive monitoring to ensure policies evolve with real-time sector data.

SMEs Vulnerabilities (10-15% Exits)

Data: 57% cut portfolios (leading to 10-15% exits); 53% R&D reduction.

10-15% SMEs reduction projection.

6. INDUSTRY AND FUTURE DEVELOPMENTS

SMEs represent approximately 92% of the European medical device sector, yet they bear a disproportionate share of regulatory burden. Obligations under Article 10 MDR/IVDR, combined with clinical evidence requirements, PMS duties, and EUDAMED readiness, consume resources that SMEs often lack.

In 2025, many SMEs postponed EU launches, reduced product portfolios, or prioritised non-EU markets with more predictable timelines.

Under IVDR, these dynamics were particularly pronounced, affecting diagnostics essential for early detection and personalised medicine.

Access of SMEs to funding is heavily affected by the inability to forecast budget and return of investment, qualifying health innovation as high risk due to compliance burden from investors point of view.

SMEs seek survival in a system where timing, cash flow, and predictability determine whether innovation can be sustained.

Postponed EU Launches and Prioritization of Non-EU Markets

SMEs delayed EU entries due to unpredictable timelines (avg. 18 months), shifting to non-EU (e.g., US/Asia) with faster paths.

Data: EU first-launch drop: 12% SMEs IVD, 19% SMEs MD; 40% large IVD, 33% large MD (survey of 96 MD/52 IVD firms); timelines: ~18 months IVDR QMS/TDA, leading to postponements.

Data: 25% SMEs report withdrawals/postponements; 60% cite unpredictability causing non-EU priorities (survey of 200 Italian firms, 94% SMEs).

Reduced Product Portfolios

Data: 57% reduced portfolios (69% large, 13% SMEs implying cuts); 24% ceased EU production (leading to 10–15% exits); IVDR orphan: 26.6% <5% transition.

: 25% SMEs reduced portfolios/withdrew; IVDR diagnostics: 15% market reduction for personalized medicine.

Funding Access Affected by Unpredictability and High-Risk Perception

Compliance burdens make forecasting impossible, labelling innovation high-risk.

- **Data**: 72% micro/SMEs cite burdens as funding barrier; 54% unpredictable timelines; costs up 100% (qualifying as high-risk, per investor views).
- **Data**: 176,202 MD TDA costs; 55% SMEs flag as top challenge, making funding high-risk.

SMEs Seek Survival in Timing/Cash Flow/Predictability System

System unpredictability threatens sustainability, especially IVDR.

- **Data**: 38% SMEs struggle with regulatory staff (cash flow drain); 53% R&D reductions for survival; 24% cease production.
- **Data**: 72% administrative burden; 54% timeline issues; 10–15% exit risk.

Key Developments for 2026

Several developments are expected to shape the regulatory environment in 2026:

- EUDAMED: From 28 May 2026, the first four EUDAMED modules (Actor Registration, UDI/Device Registration, Notified Bodies and Certificates, and Market Surveillance) become mandatory, following the end of the transitional period triggered by Regulation (EU) 2024/1860. This represents a significative shift toward greater transparency and

traceability, while also posing short-term implementation challenges for manufacturers and authorities.

- EMA and Breakthrough Devices: The European Medicines Agency is expected to launch a pilot programme in 2026 linked to the implementation of guidance on Breakthrough Devices (BtX), with a focus on enhanced coordination, expert panel involvement, and support for innovative products addressing unmet medical needs, including biotech–MedTech hybrids.
- Notified Body Capacity and Harmonisation: Following potential adoption of the Commission's simplification measures, stakeholders anticipate gradual improvements in assessment throughput and consistency. However, capacity constraints are expected to persist in the near term, particularly for high-risk devices and IVDR certifications.

Regulatory performance must be judged by its ability to deliver safe innovation to patients within clinically meaningful timeframes.

7. ROMANIA

We have examined the Romanian institutional and legal landscape because EU-level regulatory reforms only materialise through national systems, and Romania illustrates—with unusual clarity—how structural constraints, institutional gaps, and financing realities shape the real-world consequences of MDR/IVDR on SMEs, healthcare providers, and ultimately patients. While the regulatory obligations are European, their execution is national, and Romania combines several stress factors: the absence of a domestic notified body, limited regulatory throughput, parallel cybersecurity obligations under NIS2, and a healthcare system undergoing rapid digitalisation through EU funding instruments.

Romania therefore functions as a high-sensitivity test case for assessing whether recent and proposed EU reforms—aimed at reducing burden, improving predictability, and accelerating innovation—can deliver tangible effects where institutional capacity is thin and compliance risk is structurally amplified. The interaction between the medical device authority (ANMDMR), the cybersecurity supervisor (DNSC), EU funding under the PNRR, and non-state stabilisers such as clusters reveals how regulatory friction, financing constraints, and innovation policy converge at national level.

Analysing Romania is therefore not a local detour but a stress test for EU regulatory design: it highlights where simplification measures succeed, where implementation risk persists, and how delays or inconsistencies translate into reduced SMEs investment appetite, slower hospital adoption of certified technologies, and delayed patient access to advanced diagnostics and digital medical tools. In this environment, intermediary actors such as ROHEALTH emerge not as peripheral stakeholders, but as functional substitutes for missing institutional capacity—underscoring that, under MDR/IVDR conditions, ecosystem resilience becomes a regulatory variable.

Context

Romania provides a revealing national perspective on MDR/IVDR implementation. As a Member State without a domestic notified body, Romania is structurally dependent on cross-border conformity assessment capacity. This dependency amplifies any inefficiency or delay occurring at EU level.

National authorities focus primarily on market surveillance and vigilance, while certification pathways remain external. For Romanian innovators, hospitals, and importers, access to innovation is therefore tightly coupled to EU-wide system performance.

Institutional and legal landscape

The National Agency for Medicines and Medical Devices of Romania (ANMDMR) acts as the competent authority for MDR and IVDR implementation, overseeing vigilance and post-market activities. Romania has no domestic notified body, making it structurally dependent on cross-border certification capacity.

In parallel, Romania transposed the NIS2 Directive through OUG 155/2024, introducing binding cybersecurity obligations under the supervision of the National Cyber Security Directorate (DNSC). For hospitals deploying digital medical devices and software, compliance with MDR/IVDR now intersects directly with cybersecurity governance.

Romania also transposed NIS2 through OUG 155/2024, introducing binding cybersecurity obligations enforced by DNSC, directly affecting hospitals and digital medical device deployments.

PNRR- Romania National Recovery and Resilience Plan, financing and digital health

Romania's PNRR allocates substantial funding to healthcare digitalisation, (**Pillar 5: Health and Institutional Resilience** Total allocation: **2.45 billion** (8.6% of total PNRR 28.5 billion))

including hospital IT systems and interoperability. These investments can support MDR/IVDR obligations (PMS, traceability, real-world evidence), but only if regulatory throughput allows timely deployment of certified technologies.

Financing SMEs from other sources is difficult as the health products that need CE mark are considered high risk investment due to the uncertainty of the compliance process time and result.

Romania currently does not operate a formally established regulatory sandbox for artificial intelligence, including for AI-enabled medical devices, but it has several institutional, strategic, and infrastructural elements that could support its rapid creation.

At policy level, the National Artificial Intelligence Strategy 2024–2027 explicitly commits to the development of regulatory sandboxes and testing environments, acknowledging that Romania presently lacks operational facilities for controlled AI experimentation.

From an institutional perspective, Autoritatea pentru Digitalizarea Romaniei (ADR) manages large-scale digital transformation initiatives—such as government AI-enabled platforms, interoperability infrastructure, and SMEs digital skills programmes—that could provide the technical and organisational backbone for a future AI Act–compliant sandbox.

In parallel, the medical device regulatory authority, ANMDMR, already operates established mechanisms for clinical investigations, vigilance, and innovation support (including cooperation with the Health Innovation Hub), but these mechanisms do not currently amount to a regulatory sandbox with controlled derogations or structured real-world testing.

As a result, while Romania meets the strategic and infrastructural preconditions for an AI regulatory sandbox—particularly relevant for SMEs and AI medical device developers— by linking national efforts to Testing and Experimentation Facilities (TEFs) and the European Digital Innovation Hubs (EDIHs) network;

These connections are recognised as important for SMEs and startups seeking regulatory guidance, technical support, and compliance pathways before market entry. Overall, the strategic and infrastructural foundation for a regulatory sandbox is forming—rooted in national strategy and ADR's digital transformation projects—but operationalisation and formal governance aligning Romania with the EU AI Act's August 2, 2026, sandbox establishment deadline, at the date of this report remains work in progress.

Clusters as system stabilisers

Clusters such as ROHEALTH play a critical role in Romania by compensating for missing national capacity. They help SMEs navigate regulatory requirements, connect hospitals with innovators, aggregate demand, and link national actors to EU projects and expertise.

ROHEALTH participated in the development of the 122 M Euro call under the Sectoral Operational Program (SOP) dedicated to scaling up medical devices developed by SMEs. This call included, for the first time, eligible expenses for necessary regulatory costs (such as consultancy and Notified Body taxes) and imposed an obligation on fund recipients to submit the technical file for obtaining the CE mark.

By covering regulatory expenses, this call directly bolsters innovation growth through structured compliance pathways. It enables SMEs to navigate MDR/IVDR requirements more efficiently, allocating resources to R&D and product refinement while ensuring devices meet EU safety standards. ROHEALTH's data shows that funded projects have led to 40% more CE-marked devices entering clinical use, enhancing traceability and real-world evidence collection—key for sustainable MedTech advancement and resilient healthcare systems

Impact on patients

For Romanian patients, MDR/IVDR delays translate into slower access to advanced diagnostics and digital tools, reinforcing health inequities across the EU.

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(This Annex is part of the report and should be cited as such in audits and deliverables.)

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