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Triggering authored paradox in medical device governance: notified bodies, regulatory change and artificial intelligence

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Abstract

Purpose – This study examines how paradoxical tensions are institutionally embedded within EU Medical Device Regulation (MDR) and why they become salient when regulatory and technological changes converge.

Design/methodology/approach – The study analyses the adoption of artificial intelligence (AI) in European conformity assessment, focussing on notified bodies operating under the MDR, In Vitro Device Regulation and AI Act. It draws on 17 semi-structured interviews with regulatory professionals, analysis of EU legal texts and observations of regulatory practice, following an abductive analytical approach.

Findings – Five paradoxical tensions are codified within EU legal texts as parallel obligations rather than hierarchically ordered priorities. These tensions remain latent as long as regulatory work proceeds within established routines. Four governance-induced triggers (regulatory reform, workload pressure, institutional scrutiny and intensified procedural demands) collapse the arrangements that maintain latency, rendering tensions salient. AI functions as a cross-cutting amplifier across the system.

Research limitations/implications – The study is limited to EU medical device governance and draws on 17 interviews with conformity assessment professionals. The concept of authored paradox and the trigger mechanisms identified may operate differently in other regulatory regimes. Future research could examine how different legal traditions author paradox differently, and whether the same triggers produce different patterns of salience depending on enforcement intensity or organisational position.

Practical implications – Introducing AI into conformity assessment requires governance arrangements that explicitly acknowledge the contradictions AI will activate. Regulatory guidance clarifying acceptable use and accountability would reduce informal workarounds. Notified bodies would benefit from structured experimentation spaces insulated from immediate accreditation scrutiny, enabling learning without triggering the full weight of accountability arrangements.

Social implications – Regulatory systems designed to protect patient safety and public health govern through sustained contradiction rather than despite it. When these contradictions become simultaneously salient, the resulting hesitation and deferral can delay access to technologies that may benefit patients. Making deferral dynamics more transparent may support more accountable governance of emerging technologies in healthcare.

Originality/value – The study contributes to paradox theory by showing how latency is institutionally designed, by identifying the mechanisms through which governance-induced triggers activate latent paradoxical tensions and by introducing the concept of authored paradox to capture how regulatory systems deliberately embed and preserve contradiction through institutional design.

Keywords Paradox theory, Regulatory governance, Medical devices, Artificial intelligence, Innovation management, Institutional design

Paper type Research article

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1. Introduction

Paradox is a central concept in organisation and management research that examines how organisations and institutions deal with enduring, contradictory tensions (Cameron and Quinn, 1988; Poole and Van de Ven, 1989; Smith and Lewis, 2011). Rather than being resolved through choice or trade-offs, such tensions are typically interdependent and persist over time. Prioritising one side often generates opposing pressures, allowing these tensions to persist (Lewis, 2000; Farjoun, 2010). This perspective has proven valuable for understanding organisational life under conditions of complexity, uncertainty and institutional constraint, where actors are required to sustain engagement with incompatible expectations rather than eliminate them (Andriopoulos and Lewis, 2009; Raisch *et al.*, 2018).

A significant development in this literature concerns the temporal dynamics of paradox. Research has increasingly recognised that paradoxical tensions are not continuously experienced as salient in everyday organisational practice. Instead, tensions may remain latent, embedded in structures, routines and governance arrangements without being explicitly recognised as paradoxical (Schad *et al.*, 2016). This shift has redirected attention away from static typologies of paradox towards questions of when and how contradictions become salient and consequential for action. Hahn and Knight (2021) conceptualise paradox in terms of latency, salience and persistence, thereby providing an ontological account of how contradictory demands can exist prior to recognition, become activated in specific contexts and recur over time.

Regulated systems, understood here as institutionally dense configurations organised through layered roles and formal compliance requirements, offer a specific context to examine these dynamics. Regulation is widely defined as a mode of governance operating through formal rules, delegated authority and oversight mechanisms to manage uncertainty and protect public interests (Majone, 1994; Braithwaite and Drahos, 2000; Levi-Faur, 2012). A consistent finding in regulatory governance literature is that regulatory systems are designed to pursue multiple objectives simultaneously, such as public protection and market facilitation, standardisation and professional discretion, or stability and adaptability (Hood *et al.*, 2001; Levi-Faur, 2005, 2012). These objectives are not hierarchically ordered, and they are articulated within legal or regulatory texts. In practice, they are implemented through formal procedures, audits and systems of accountability (Power, 1997; Scott, 2001). Arguably, such a context shapes the relationship between salient and latent tensions (Schad *et al.*, 2016; Hahn and Knight, 2021), and as we will show, regulation can be understood as an institutional architecture in which contradictory, yet interdependent tensions are deliberately embedded.

Periods of regulatory change are likely to shape how paradoxes unfold. Regulatory change can disrupt established routines while also reshaping responsibility and expectations of accountability and defensibility (Page, 2001; Kerwin, 2003) and may therefore alter the conditions under which latent contradictions become salient. Yet despite growing recognition that context and change matter for the salience of paradoxical tensions, existing research offers limited empirical examples of how salience occurs. While paradox theory treats latency as a precondition for activation, the literature has not systematically examined how tensions are formally codified and preserved within institutional architectures prior to their activation. Paradox studies have highlighted the importance of contextual triggers (Schad *et al.*, 2016; Hahn and Knight, 2021) but have rarely examined regulatory change as a mechanism by which latent tensions become salient. Regulatory governance research, in turn, has documented intensification of oversight and rule expansion (Power, 1997; Levi-Faur, 2012) but has seldom conceptualised these developments through the lens of paradox activation. This is problematic from a theoretical perspective in the sense that we can neither understand nor explain the emergence of salient paradoxical tensions within regulated systems. It is also problematic from a practical perspective as paradoxical tensions affect many managerial decisions such as the adoption of innovation and change management.

This study addresses this gap by examining how paradoxical tensions are embedded in regulatory governance and what triggers their activation. Drawing on paradox theory and

regulatory governance scholarship, the study focuses on European Medical Device Regulation (MDR) during a period of substantial regulatory change. Empirically, the study draws on interviews with regulatory professionals, regulatory documents and accounts of conformity assessment practice. Recent reforms, such as the MDR, In Vitro Device Regulation (IVDR) and the Artificial Intelligence Act (AIA), make regulatory contradictions more visible than before, bringing issues that were previously implicit into clearer focus. At the same time, the reforms coincide with rising expectations that conformity assessment practice should itself be transformed through AI to improve efficiency and reduce assessment backlogs. This dual movement intensifies pressures on how regulatory work is organised and performed in practice. The transformation of MDR thus provides a particularly suitable empirical setting for examining how long-standing, institutionally embedded tensions shift from latency to salience.

Accordingly, the study addresses the following research questions:

RQ1. How are paradoxical tensions institutionally embedded and stabilised within EU MDR?

RQ2. Why do latent paradoxical tensions become salient in regulatory systems?

2. Overview of the literature

2.1 Regulatory governance, innovation and artificial intelligence

Regulation is typically understood as a distinctive mode of governance designed to manage uncertainty, risk and competing societal objectives through formal rules, delegated authority and oversight mechanisms (Majone, 1997; Baldwin and Cave, 1999; Braithwaite and Drahos, 2000; Levi-Faur, 2012). Regulatory governance scholarship emphasises that contemporary regulation extends beyond the state, operating through hybrid constellations of public authorities, private actors, standards bodies and procedural infrastructures that together shape how responsibilities are allocated, monitored and justified over time (Scott, 2004; Jordana and Levi-Faur, 2004).

Regulatory systems are deliberately designed to pursue multiple objectives simultaneously (Jordana and Levi-Faur, 2004). In domains characterised by high uncertainty and high stakes, such as healthcare and medical technologies, regulatory frameworks articulate commitments to public protection, safety and accountability alongside expectations related to innovation, efficiency and market access (Majone, 1997; Moran, 2003; Vogel, 1996). These objectives are not resolved through explicit prioritisation. Rather, they are institutionalised in parallel through legal texts, standards and procedural requirements that give effect to multiple evaluative logics at once (Power, 1999; Hood *et al.*, 2001). Regulation thus operates by embedding different goals and requirements in legal texts.

Regulatory governance scholarship has shown that such architectures rely heavily on implemented procedures, such as verification and auditability. Through mechanisms such as documentation requirements, conformity assessment and ongoing oversight, regulatory systems translate abstract objectives into repeatable and defensible practices (Power, 1999; Jordana and Levi-Faur, 2004). These mechanisms allow regulatory work to proceed without requiring actors to confront underlying contradictions directly. As a result, competing demands can remain institutionally stabilised for extended periods, even as technologies, organisational practices and expectations evolve.

The innovation and intended adoption of radically new technologies stress the regulatory system. A case in point is the increasing relevance of artificial intelligence (AI) to conformity assessment work. AI tools are increasingly discussed as means of improving efficiency in regulatory processes such as documentation review, consistency checking and assessment preparation (Gilbert *et al.*, 2023; Li *et al.*, 2026). At the same time, the use of AI within regulatory work raises fundamental concerns related to accountability, transparency and

defensibility, particularly in contexts where assessment decisions have direct implications for patient safety. Regulatory responses to AI therefore do not introduce wholly new objectives but may increase existing tensions between, for example, innovation and control, discretion and standardisation, and flexibility and accountability. These tensions are not merely incidental side effects of technological change but are embedded within the architecture of regulatory governance itself.

A case in point is the AIA that has attracted growing scholarly attention as an instance of this regulatory logic. Early analyses noted that the Act adopts a risk-based tiering approach but delegates the specification of its requirements to European standardisation bodies, leaving the practical meaning of compliance to be determined outside the legislative text (Veale and Zuiderveen Borgesius, 2021). Floridi (2021) observed that the Act's philosophical approach combines ethical principles derived from the High-Level Expert Group on AI with a market-oriented risk framework, producing a regulatory instrument that simultaneously pursues protection and innovation without resolving the tension between them. Smuha (2021) situated the AIA within a broader dynamic of regulatory competition, arguing that the EU's pursuit of trustworthy AI serves both as an ethical commitment and as a strategy for establishing global regulatory leadership, a dual ambition that embeds competing objectives into the regulatory architecture itself.

The governance implications of the AIA for conformity assessment have received limited but relevant attention. Laux *et al.* (2024a) argued that the Act conflates trustworthiness with the acceptability of risk, reducing a complex relational concept to a procedural question resolved through conformity assessments conducted by technical experts. This conflation is consequential for notified bodies, which are tasked with operationalising this narrow understanding of trust precisely. In a related study, Laux *et al.* (2024b) identified three possible pathways for standardisation under the AIA and showed that each requires answering normative questions about transparency, fairness and accountability that the legislative text itself leaves open. This suggests that the conformity assessment system will absorb unresolved normative tensions from the regulatory framework, a dynamic consistent with the concept we later will refer to as authored paradox.

Within the medical device domain, research has begun to map the interaction between the AIA and existing regulatory frameworks, although most literature on AI and regulation is focused on the use of AI in devices as opposed to AI for regulation (Mauritzon and Guo, 2026). Luckner and Lauer (2025) examined the regulatory classification of AI-enabled products under the AIA and MDR/IVDR, showing how dual classification requirements create overlapping governance demands. Schmidt *et al.* (2024) mapped the broader regulatory landscape for AI in health across the EU, identifying a baseline framework composed of data, technology, innovation and health policy but noted that regulation specifically pertaining to AI remains nascent. Comparative analyses of regulatory frameworks across jurisdictions have also emerged (Han *et al.*, 2024; Zhou and Gattinger, 2024), though these tend to treat regulation as a textual and procedural system rather than as a site of professional practice or institutional tension. The only study in the recent literature that explicitly addresses notified bodies in the context of the AIA concerns the Act's provisions for notifying authorities rather than the use of AI within conformity assessment practice (Palma Ortigosa, 2024).

2.2 Paradox theory and institutional latency in regulation

Paradox theory provides a well-established conceptual lens for analysing configurations characterised by persistent, contradictory, yet interdependent demands (Lewis, 2000; Smith and Lewis, 2011; Schad *et al.*, 2016). Rather than treating contradiction as a problem to be resolved, paradox theory emphasises endurance, simultaneity and mutual dependence as defining features of organisational and institutional life. This perspective has been widely applied in studies of innovation, governance and institutional change, where actors must

engage with competing demands that are each legitimate and necessary (Andriopoulos and Lewis, 2009; Farjoun, 2010; Jarzabkowski *et al.*, 2013a). The paradox perspective intersects with research on exploration-exploitation (March, 1991; Levinthal and March, 1993), organisational ambidexterity (Tushman and O'Reilly, 1996; Raisch and Birkinshaw, 2008) and dialectical approaches to change (Benson, 1977; Putnam *et al.*, 2016), each of which addresses persistent contradictions but from different theoretical starting points.

Recent developments in paradox research have refined its temporal and ontological dimensions. Scholars increasingly emphasise that paradoxical tensions are not continuously salient but may remain latent for extended periods before becoming consequential for action (Schad *et al.*, 2016; Jarzabkowski *et al.*, 2013b). Hahn and Knight (2021) conceptualise paradox in terms of latency, salience and persistence, arguing that contradictory demands can exist as latent potentialities embedded in socio-material and institutional arrangements, becoming salient only under specific conditions of enactment. From this perspective, latency does not imply absence but a state in which contradictions are stabilised through arrangements that prevent them from becoming simultaneously salient.

Applied to regulatory governance, latency can be framed as an institutional condition rather than a cognitive one. Regulatory systems stabilise contradiction through procedural sequencing, divisions of responsibility and the distribution of accountability across actors and organisational levels. Legal provisions, standards and guidance documents translate multiple regulatory objectives into durable and portable rules that can be repeatedly applied across cases without requiring their underlying tensions to be explicitly addressed (Majone, 1997; Power, 1999). This institutional containment enables regulatory systems to maintain both control and adaptability in complex and risk-sensitive domains.

From a paradox perspective, such arrangements do not eliminate contradiction but enable its persistence. By separating evaluative moments and allocating responsibility across organisational boundaries, regulatory systems maintain the interdependence of competing objectives while limiting their simultaneous enactment (Smith and Lewis, 2011; Jarzabkowski *et al.*, 2013a), particularly in contexts where legitimacy depends on demonstrating both rigour and responsiveness (Power, 1999; Scott, 2004). When regulatory conditions change, through new legislation, delegated acts or revised guidance, the scope for such separation narrows. Salience therefore does not imply new contradictions but a shift in the conditions under which existing ones become jointly relevant for action (Hahn and Knight, 2021; Schad and Bansal, 2018).

Importantly, heightened salience in regulated settings does not necessarily manifest as overt conflict or resistance. Rather, tensions may become consequential through subtle shifts in practice, including increased institutionalisation, expanded justification work and heightened attention to auditability (Lewis, 2000; Smith and Lewis, 2011). In regulatory contexts, such shifts reflect an ongoing pattern in which paradoxical tensions persist and are periodically reactivated.

3. Methods

3.1 Research setting

This study examines how paradoxical tensions embedded in European MDR remain latent and how they become salient during periods of regulatory change. The empirical setting is European medical device conformity assessment, with a particular focus on notified bodies and associated regulatory actors operating under the MDR, IVDR and the European AIA. The study concerns the use of AI in conformity assessment work performed by notified bodies, rather than the regulation of AI-enabled medical devices as products. While both dimensions are relevant to the regulatory system, the analytical focus is on how AI is adopted and experienced within assessment practice.

The European medical device regulatory system combines EU legislation with delegated assessment and professional judgement within a market-based system

(Majone, 1994; Scott, 2001; Levi-Faur, 2012). Notified bodies (NBs) occupy a central position within this system as private organisations designated by national authorities to conduct conformity assessments for the European Union. They are accountable to national regulators, known as competent authorities (CAs), as well as to manufacturers and professional standards. This configuration makes the setting particularly suitable for examining paradoxical tensions that are embedded in regulatory design but are not continuously experienced as problematic in everyday practice.

The study focuses on the period following the introduction and implementation of the MDR and IVDR, which expanded regulatory requirements and documentation while significantly strengthening oversight mechanisms (European Parliament and Council, 2017a, b). These reforms altered the conditions under which conformity assessment work is performed and reshaped accountability relations within the regulatory system.

3.2 Data collection

The empirical material was collected from professionals working within, or closely with, European notified bodies involved in medical device and in vitro diagnostic conformity assessment. Data were collected between March 2023 and March 2025 and include interviews, regulatory documents and observations, suitable for analysing complex governance settings (Creswell, 2013).

The semi-structured interviews included 17 participants from 7 notified bodies and 5 companies in the medtech regulations industry that support manufacturers: auditors, technical assessors, regulatory managers and consultants. Participants were selected using purposive sampling based on their professional role, some exposure to the implementation of AI in conformity assessment and experience with conformity assessment under MDR and IVDR. Interviews lasted between 60 and 90 min and were conducted in English or Swedish, either in person or via video conferencing. The sample size was delimited by the small population of NB professionals with direct AI-relevant experience within the current regulatory framework; analytical consistency across accounts was observed as data collection progressed. At the time of data collection (March 2023 to March 2025), the number of notified bodies designated under the MDR grew from 38 to 49 following which the number rose again to 52 early in 2026. IVDR designations remained considerably lower, rising from 10 to 12 during the same period and then rising again to 19 (European Commission, 2026). Some notified bodies hold designations under both regulations. These organisations vary in size, from smaller bodies with limited staff to large international certification organisations with several hundred employees. Within each notified body, conformity assessment is carried out by a limited number of specialised auditors and technical assessors, with managerial and quality oversight staff constituting a further layer. Moreover, the subset of professionals with direct experience of AI-related aspects of conformity assessment, whether through encounters with AI-enabled devices, emerging AI tools for assessment work or engagement with the AIA's implications, was limited at the time of the study.

Recruitment drew on the first author's professional network and was extended through snowball referrals. As data collection progressed, analytical consistency across accounts was observed, with participants from different organisations and roles describing similar tensions, constraints and sources of uncertainty. While the sample cannot claim statistical representativeness, its composition reflects the relevant professional community engaged with AI-related conformity assessment questions during this period.

The interview guide (Appendix 1) focused on participants' descriptions of regulatory work, experiences of regulatory change and perceptions of evolving assessment practices. The questions were designed to elicit accounts of everyday work, moments of uncertainty, disruption or difficulty, allowing contradictions to surface through participants' own narratives. This approach aligns with interpretive qualitative research that prioritises actors'

sensemaking while maintaining analytical distance (Alvesson and Sköldberg, 2018). All interviews were recorded, transcribed verbatim and anonymised.

In parallel, a corpus of regulatory documents was collected. Documents were selected based on three criteria: (1) legal authority, binding EU legislative texts (MDR, IVDR, AIA) and their implementing and delegated regulations, which define the formal requirements within which conformity assessment operates; (2) interpretive guidance, documents issued by the Medical Device Coordination Group, which translate legislative provisions into operational expectations for notified bodies and other actors; and (3) sectoral relevance, publicly available documents from industry associations (e.g. MedTech Europe) and notified body associations (e.g. Team-NB) that articulate professional positions, capacity concerns and implementation challenges. These documents are treated as institutional artefacts through which regulatory expectations and contradictions are formalised and stabilised (Czarniawska, 2004). They articulate regulatory objectives, procedural requirements and accountability structures and were analysed both as context for the interview material and as sites where paradoxical tensions are embedded in formal regulatory language.

In addition, the first author attended five professional events related to MDR and conformity assessment, including conferences, expert panels and dialogues with CAs. Specific event details are limited to preserve anonymity and to follow ethical guidelines. Observational field notes were produced to capture concerns, shared framings and collective sensemaking processes. These materials were used to contextualise interview accounts and trace how regulatory expectations and concerns circulate across professional forums, rather than as standalone sources of evidence. Table 1 provides an overview of the empirical material.

3.3 Data analysis

The study followed an abductive analytical approach (Dubois and Gadde, 2002; Alvesson and Sköldberg, 2018; Reichertz, 2014) to examine how paradoxical tensions are embedded in regulatory governance and how they become salient. The analysis did not test predefined hypotheses, nor did it rely solely on inductive theory building. Instead, it proceeded through continuous comparison between empirical material and concepts from paradox theory, particularly latency, salience and persistence. The interviews identified salient paradoxical tensions, legal texts showed embedded paradoxes and the observational notes as well as interview text were used to triangulate the findings from the respondents.

Analysis began with close reading of interview transcripts, regulatory documents and field notes. Initial coding was performed by the first author and stayed close to the language used in the material, focussing on descriptions of regulatory change, disruption of routines and difficulties in balancing competing demands. Attention was paid to moments where established ways of working were described as insufficient, for example through references to uncertainty, increased justification, escalation or constrained professional judgement. Coding was conducted manually to maintain proximity to the empirical material and was carried out using word-processing software with a structured coding log.

Table 1. Overview of data sources

Data source	Description	Quantity/Duration
Semi-structured interviews	Auditors, technical assessors, managers and consultants with AI and conformity-assessment experience	17 interviews (60–90 min each)
Documentary material	EU MDR/IVDR texts, MedTech Europe and Team-NB reports, accreditation body statements	12 documents
Observations	Conferences, panels and expert meetings on AI in conformity assessment	5 events (1–2 days each)

Source(s): Authors' own work

The coding proceeded in three phases. In the first phase, descriptive codes were assigned to segments of text reflecting participants' accounts of their work, experiences of change and encounters with regulatory demands (e.g. "increased documentation burden," "uncertainty about AI classification," "conflicting expectations from CA and manufacturer"). In the second phase, codes were grouped into broader categories reflecting patterns of tension (e.g. "standardisation vs. judgement," "transparency vs. commercial sensitivity," "capacity vs. scope expansion"). In the third phase, these categories were compared with paradox theory concepts to develop the analytical framework. The coding scheme evolved iteratively throughout the analysis: initial codes were revised, merged or split as the relationship between empirical patterns and theoretical concepts became clearer.

Coding was conducted by the first author, who has professional experience in MDR. To mitigate the risks associated with a single-coder approach, regular analytical discussions were held with the co-authors, during which coded excerpts, emergent categories and interpretive decisions were reviewed and challenged. These discussions served as a form of peer debriefing (Lincoln and Guba, 1985) and helped to surface assumptions rooted in the first author's professional proximity to the field. Additionally, analytic memos were written throughout the process, recording the reasoning behind coding decisions, alternative interpretations considered and how specific tensions were distinguished from one another. These practices constituted an audit trail that documents the analytical pathway from raw material to findings.

Regulatory documents were examined to identify how contradictory demands were articulated and stabilised through legal provisions, guidance and procedures. This allowed paradoxical tensions to be treated as institutionally embedded conditions rather than as individual interpretations and to distinguish between latent contradictions in regulatory design and their later salience in practice.

As analysis progressed, material was compared across interviews and documents to identify contradictions across roles and organisational settings. Tensions were identified as contradictory yet interdependent demands that persisted within the regulatory system. Documents were used to examine how these tensions were embedded in formal rules, while interviews were used to examine when and how they became salient in regulatory work. The identification of triggers followed the same abductive logic. Empirical accounts of disruption or hesitation were treated as analytical entry points rather than as evidence of predefined mechanisms. Throughout the analysis, interpretations were refined through iterative comparison across data sources and discussion among the authors. The full analysis mapping each trigger to its primary and secondary tension activations, including empirical manifestations and illustrative evidence, is provided in Appendix 2 (Table A1).

Analytical credibility was addressed through reflexivity and transparency (Alvesson and Sköldberg, 2018). The first author's professional background in MDR facilitated access and supported detailed understanding of regulatory work, while requiring continuous reflection on taken-for-granted assumptions. Reflexivity was supported through analytic memo writing and regular discussions with co-authors who were less embedded in the regulatory context. The use of multiple data sources further supported credibility by situating interview accounts within their broader institutional context (Creswell, 2013).

4. Findings

4.1 Overview: latent paradox and triggered salience in regulatory work

The findings show that paradoxical tensions are a persistent feature of EU MDR, but they are not continuously experienced as problems in regulatory work. Instead, these tensions are institutionally embedded within legal texts, regulatory procedures and governance arrangements, where they remain largely latent. They become salient when changes in conditions disrupt established routines and render contradictory demands simultaneously consequential for action.

Across the empirical material, five paradoxical tensions were identified: (1) protection and safety versus innovation and access, (2) exploration versus exploitation, (3) collaboration versus isolation, (4) efficiency versus quality and (5) autonomy versus control (Table 2). These tensions were observed to be activated through four triggers: regulatory reform, workload and resource pressure, heightened institutional scrutiny and intensified procedural and organisational demands. Across multiple trigger categories, the increasing presence of AI in conformity assessment work acted as a cross-cutting amplifier, sharpening existing contradictions without itself constituting a discrete trigger. Sections 4.5–4.9 present each trigger-tension pairing in turn, while the relationships between the tensions and AI are documented in Appendix 2 (Table A1). Below, we first discuss the embeddedness of paradoxical tensions, followed by showing how they were triggered into salience.

Table 2. Paradoxical tensions embedded in EU medical device governance

Paradoxical tension	Description	EU legal framework	How the framework manifests the tension
Protection and safety ↔ Innovation and access	The system simultaneously seeks to ensure protection of health and safety while supporting innovation and timely access. These objectives are parallel and non-hierarchical	MDR Art. 1(1); IVDR Art. 1(1); Reg. 2023/607 Recital (5); AI Act Recital (6)	Safety, public health and innovation articulated as concurrent objectives. Transitional amendments preserve market access without lowering safety requirements
Exploitation (standardisation) ↔ Exploration (learning and adaptation)	Regulatory work depends on stable, standardised procedures while also requiring ongoing learning and adaptation in response to technological novelty	MDR Annex I (GSPRs); MDCG guidance; AI Act Art. 9 (1); AI Act Recital (65)	Fixed conformity assessment routes coexist with lifecycle-based obligations and non-binding guidance. Continuous risk management mandated without revising the core legal text
Transparency and traceability ↔ Confidentiality and data protection	Expanded transparency requirements support vigilance and trust, while data protection rules restrict processing and disclosure of sensitive data	MDR Art. 33 (EUDAMED); MDR Art. 109; GDPR Art. 5 (1)(c); GDPR Art. 9(1)	Public databases increase information availability, while The General Data Protection Regulation (GDPR) imposes strict data minimisation limits. No mechanism for reconciling these objectives
Independence and impartiality ↔ Collaboration and coordination	NBs are required to maintain strict independence, while consistent regulatory outcomes depend on coordination and shared interpretation	MDR Art. 35(5); IVDR Art. 31(5); MDR Art. 57 (MDCG)	Legal requirements enforce distance from manufacturers and prohibit conflicts of interest, while parallel provisions establish coordination structures
Local autonomy and discretion ↔ Central control and harmonisation	Regulatory authority is decentralised to national authorities and NBs, while harmonised rules centralise control at the EU level	MDR Art. 101; MDR Art. 33; AI Act risk classification provisions	National authorities retain enforcement responsibility and discretion but operate within increasingly centralised infrastructures and oversight mechanisms

Source(s): Authors' own work

4.2 Paradoxical tensions embedded in EU Medical Device Regulation

Analysis of EU MDR shows that paradoxical tensions are not merely experienced in regulatory practice but are institutionally embedded within the legal framework itself. Across the MDR, IVDR, associated guidance and related regulatory instruments, contradictory yet interdependent objectives are explicitly articulated and preserved within the same legal texts.

At the most general level, the regulatory framework simultaneously mandates a high level of health protection and the facilitation of innovation and market access, corresponding to the first paradoxical tension of protection and safety versus innovation and access. This dual objective is stated directly in the purpose of the MDR. Article 1(1) specifies that the Regulation aims to:

> . . . establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation (Regulation (EU) 2017/745, Art. 1(1)).

Rather than prioritising one objective over the other, the Regulation articulates safety and innovation as parallel obligations. The legal text does not specify how potential conflicts between these objectives are to be resolved in practice, thereby stabilising a persistent contradiction within the regulatory framework itself. Here, protection and innovation are not framed as sequential priorities but as coexisting obligations.

This contradiction is further reinforced through subsequent regulatory amendments introduced to address system strain without revising the underlying objectives. Regulation (EU) 2023/607, adopted in response to capacity constraints within the conformity assessment system and the risk of device shortages following the introduction of the MDR and IVDR, explicitly states that the extension of transitional provisions aims to:

> ensure a high level of public health protection, including patient safety and an avoidance of shortages of medical devices needed for the smooth functioning of healthcare services, without lowering current quality or safety requirements (Regulation (EU) 2023/607, Recital (5)).

Here, the Regulation simultaneously acknowledges the risk of supply disruption and reaffirms uncompromised safety and quality standards. Rather than resolving the tension between access and protection, the amendment preserves both objectives in parallel, thereby stabilising the contradiction as a latent and durable feature of EU medical device governance.

The tension between exploitation and exploration is embedded through the combination of fixed conformity assessment procedures and interpretive guidance. Core legal requirements define standardised assessment routes, while non-binding guidance and lifecycle obligations are introduced to support learning and adaptation, particularly in relation to emerging technologies. The AIA reinforces this structure by explicitly combining risk-based classification with ongoing post-market obligations:

> In order to ensure a consistent and high level of protection of public interests such as health, safety and fundamental rights, while supporting innovation, this Regulation lays down harmonised rules for the placing on the market, putting into service and use of artificial intelligence systems in the Union following a risk-based approach (Regulation (EU) 2024/1689, Recital (6)).

Further paradoxical tensions are embedded through transparency and traceability requirements alongside strict data protection and confidentiality obligations. The GDPR establishes strict principles governing data use, including the requirement that personal data be "adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed" (Regulation (EU) 2016/679, Art. 5(1)(c)). In addition, the Regulation introduces a general prohibition on the processing of special categories of personal data, including health and biometric data (Regulation (EU) 2016/679, Art. 9(1)). These objectives coexist within the regulatory framework without mechanisms for reconciliation, leaving their practical balancing to regulatory actors operating across overlapping regimes. Table 2 summarises the five embedded tensions.

These findings suggest that paradoxical tensions are structurally embedded and stabilised within EU MDR itself. As long as regulatory work proceeds within established routines, these tensions remain encoded in legal texts rather than experienced as immediate problems in everyday regulatory practice.

4.3 Latent paradox in routine regulatory practice

While paradoxical tensions are demonstrably embedded in regulatory texts, interview and observational material indicate that these contradictions are not continuously experienced as problems in everyday regulatory work. Prior to triggering events, tensions were often absent from participants' accounts or treated as settled features of the regulatory environment rather than as issues requiring reflection or deliberation.

Several participants described their work in procedural terms, emphasising adherence to established routines, checklists and standard operating procedures, without articulating tensions between competing regulatory objectives. In these accounts, safety, compliance, independence and quality were treated as self-evident priorities rather than as potentially conflicting demands. As one participant noted when asked about balancing innovation and regulatory responsibility:

> That's literally the job. You follow the requirements and make sure patients are getting access to safe medical devices. That's why I get up every day. (n15)

Observational material from conferences and professional meetings similarly revealed limited explicit discussion of underlying contradictions during routine regulatory periods. Discussions tended to focus on technical clarifications, implementation timelines and procedural updates, while broader questions about trade-offs between access, innovation and protection remained largely unarticulated, a pattern consistent with the latency of embedded tensions rather than their absence.

4.4 From latent tensions to salient concerns: triggers of activation

Across interviews, documents and observational material, four triggers were identified. Triggers were identified when participants explicitly linked a change in context to heightened awareness of contradiction, increased hesitation, frustration or moral discomfort or to a perceived narrowing of acceptable action. Observational material reinforced these accounts, capturing shared concerns, cautious language and collective uncertainty in discussions of regulatory change. Given the combination of perceived opportunities and substantial uncertainty, these dynamics became especially acute when discussions turned to the potential use of AI in conformity assessment work.

4.5 Regulatory reform as a trigger: protection and innovation

Regulatory reform emerged as a primary trigger activating the tension between protection and innovation. The introduction of the MDR and IVDR was repeatedly described as a moment that shifted this contradiction from a background condition to a salient concern.

Participants described how expanded documentation requirements, intensified procedural oversight and stricter audit regimes redirected organisational attention towards compliance and defensibility. While innovation remained an articulated institutional objective, regulatory reform narrowed the perceived space for innovation within notified body work. As one auditor explained:

> The auditing role focuses on compliance, not fostering innovation. Even though that is why I took this job in the first place, to bring innovation to market. (n2)

Here, regulatory reform did not eliminate innovation as a goal but made the contradiction between innovation and regulatory responsibility explicit and consequential. Supporting

documents reinforced this shift by emphasising traceability, standardisation and procedural accountability within the NB, with withdrawal of accreditation and loss of employment as a persistent threat should the NB fail to comply.

In this context, some participants described informal, individual-level experimentation with AI tools for administrative tasks to keep up, while simultaneously emphasising that such practices lacked institutional legitimacy, which further heightened perceived tensions:

> I use AI to organise emails and speed up small tasks, but it's not something we're officially allowed to incorporate into our workflow. (n1)

Regulatory reform thus functioned as a trigger by sharpening the contrast between the regulatory framework's parallel commitment to innovation and safety and the constrained organisational action available to regulatory professionals.

4.6 Workload and resource pressure as a trigger: exploration and exploitation

Workload intensification and resource scarcity constituted a second trigger activating the tension between exploration and exploitation. The expanded scope increased assessment volumes under constrained resources.

Participants described how rising workloads narrowed the space for exploratory learning and experimentation. New technologies such as AI were framed simultaneously as necessary and unattainable under current conditions:

> We should use AI, but that would mean getting everyone on board, and it's just too much. We've discussed doing something about AI, but we have our way of doing things, and if we try something new it would become a whole change project. We don't have time for that right now . . . I know how stupid that sounds. (n10)

In several accounts, AI was articulated as a potential solution to capacity constraints while remaining incompatible with existing routines:

> I am sure we could get so much more done with AI, we could shorten the process by weeks. Perhaps months . . . but you know every little change in how we do things is a huge change in our SOPs [Standard Operating Procedures] and that's a problem for the CA [Competent Authority]. It's a problem that we don't have time for this, we are putting the buckets out for the leaky roof without fixing the hole, you know? (n17)

Workload pressure operated as a trigger by forcing professionals to confront the contradiction between maintaining established routines and developing new capabilities.

4.7 Institutional scrutiny as a trigger: collaboration and isolation

Heightened institutional scrutiny activated the tension between collaboration and isolation. This scrutiny heightened awareness of constraints on collaboration, particularly as AI-related work increasingly required dialogue and shared interpretation:

> I wish we could collaborate more with manufacturers to solve issues earlier in the process, but we're not allowed! (n5)

Even initiatives intended to encourage early dialogue were experienced as risky:

> We're not allowed to speak to our clients. As a former R&D engineer, this is frustrating because I know I could help. But we have to keep a clear distance, so it's easier not to say anything at all. (n1)

Industry actors described similar experiences of constrained exchange:

> You go to an information session led by the Notified Body and it goes for like 30 minutes with the NB person going on and on about how terrible the technical dossiers are and what they expect, and then a manufacturer asks a specific question, one that would really help a lot, and the NB person goes, "sorry, I can't consult." (n8)

Observations from industry events reinforced this pattern, as discussions were characterised by cautious language, partial disclosures and visible hesitation. Institutional scrutiny thus triggered salience by reframing collaboration as a professional risk rather than a neutral procedural constraint.

4.8 Procedural demands as a trigger: efficiency and quality

The tension between efficiency and quality became salient through the combined effects of workload escalation and intensified procedural requirements:

> There's a constant moral dilemma in balancing quality with deadlines. (n9)

Senior professionals described this tension as a persistent feature of assessment work rather than an occasional difficulty:

> What people don't always see is that even at a senior level, there's a real sense of pressure in this work. You're expected to be thorough, to stand behind your assessment, but at the same time, you're working within timelines that don't always align with that ideal. There's an ongoing stress in deciding when to stop digging, and an underlying discomfort in knowing that more time would almost always reveal more. (n14)

Concerns about variability across notified bodies further intensified this tension:

> If you were to hand in your application to one NB and the same to another, the results would likely be different. (n12)

Furthermore, procedural definitions of quality constrained the use of AI:

> AI could reduce human error and improve consistency, but we have very specific ways we have to do things. (n10)

Here, procedural demands triggered salience by exposing the gap between formally defined quality and the conditions required to sustain it in practice.

4.9 Increasing formalisation as a trigger: autonomy and control

A distinct but related trigger concerned the increasing formalisation of regulatory work itself such as expanded approval layers, performance monitoring systems and the progressive codification of professional judgement into standardised procedures. Participants described how these developments reduced the scope for discretionary action:

> We used to rely on professional judgement; now every deviation needs formal approval. (n4)

Where formalisation had not yet reached, the absence of clear procedural guidance created its own form of strain:

> There was a period where we were reviewing systems that hadn't really taken shape yet, where there isn't guidance or prior experience. You're expected to evaluate something that's still emerging, which means relying heavily on your own judgement. That level of autonomy might sound empowering, but in practice it's quite stressful because you're also responsible for ensuring control, consistency, and defensibility. You're constantly questioning whether your interpretation will hold up, not just today, but later on. (n3)

This shift transformed autonomy from a taken-for-granted feature of regulatory work into an explicit object of concern:

> It's frustrating because we have the competence, but the system doesn't let us use it. (n11)

AI was framed ambivalently, associated with both potential empowerment and further erosion of meaningful professional work:

> AI could help us make faster decisions, but it might also replace the parts of the job that make it meaningful. (n6)

4.10 Summary: triggers as activation mechanisms

Figure 1 maps the cross-cutting relationships between triggers and tensions. As the matrix illustrates, no trigger activates a single tension in isolation. Regulatory reform, workload pressure, institutional scrutiny and procedural demands each generate primary activation of specific tensions while producing secondary effects across the system. AI functioned as an amplifying condition throughout.

It should be noted that the four triggers identified in this study are not independent of one another. In this empirical case, regulatory reform functioned as a direct trigger activating specific tensions and a conditioning force that shaped the intensity of the remaining triggers. The expanded scope and heightened accountability requirements introduced by the MDR and IVDR contributed directly to the workload pressures, procedural demands and scrutiny environments described in Sections 4.6–4.9. In this sense, regulatory reform operated as a meta-trigger: a systemic change that altered the conditions under which other activation mechanisms gained force. This does not imply that workload pressure or procedural demands can only arise from regulatory reform. In other settings, these triggers could be activated by competitive dynamics, organisational restructuring or resource constraints unrelated to legal change. What is specific to this case is the cascading relationship between a large-scale regulatory transition and the concurrent intensification of multiple triggers.

The findings demonstrate that paradoxical tension salience is not static but dynamically produced through the interaction of regulatory change and professional work. In highly regulated environments, these activation mechanisms shape when emerging technologies such as AI become focal organisational concerns.

5. Discussion

This study sets out to examine how paradoxical tensions are institutionally embedded within EU MDR and why they become salient during periods of regulatory change.

This study contributes to paradox research by empirically specifying how latent paradoxes can be located within regulated systems. Prior work has emphasised that paradoxical tensions may remain latent and become salient through contextual triggers (Schad *et al.*, 2016; Hahn

Trigger	Protection ↔ Innovation	Exploration ↔ Exploitation	Collaboration ↔ Isolation	Efficiency ↔ Quality	Autonomy ↔ Control	AI as amplifier
Regulatory reform	●	○			○	○
Workload and resource pressure		●		○	○	○
Institutional scrutiny			●	○	○	○
Procedural and organisational demands	○			●	●	○

Figure 1. Trigger-tension activation matrix. Key: ● = Primary activation (dedicated findings subsection). ○ = Secondary activation (cross-cutting evidence). Empty = No direct empirical link observed. Source: Authors' own work

and Knight, 2021). The findings extend this insight by showing that latency is an experiential state and an institutional condition that is materially and textually stabilised. In EU medical device governance, contradictory objectives are explicitly codified within legal instruments and preserved over time through amendments and complementary regimes. For example, the MDR articulates safety and innovation as parallel obligations, and subsequent transitional amendments reaffirm safety while seeking to avoid shortages, thereby maintaining competing aims without resolving them (Regulation (EU) 2017/745, Art. 1(1); Regulation (EU) 2023/607, Recital (5)).

The findings demonstrate that what Hahn and Knight (2021) refer to as potential latent paradoxes are empirically observable as taken-for-granted assumptions embedded in regulatory structure. In routine work, participants frequently described regulatory practice as procedural and self-evident, with limited articulation of underlying tensions. This indicates that the persistence of paradox is a property of competing tensions and of the arrangements that enable these tensions to remain backgrounded through routines, divisions of responsibility and procedural sequencing. This strengthens the conceptual distinction between latency and salience by showing how latency is actively maintained rather than merely assumed as the absence of salience (Hahn and Knight, 2021).

The mechanism through which latency is maintained deserves emphasis. Procedural compliance functions as a substitute for substantive engagement with contradiction. As long as professionals can demonstrate adherence to documented procedures, they are not required to confront the underlying tensions that those procedures are designed to contain (Power, 1997, 1999). The audit trail becomes the instrument through which designed paradox is rendered invisible in everyday practice. Silence about tension is therefore not ignorance or denial but a practical accomplishment of regulatory governance: the system is working as designed when contradictions remain unarticulated.

A second contribution concerns the empirical specification of triggers. In paradox scholarship, triggers are often treated as loosely defined contextual changes that render tensions salient (Schad *et al.*, 2016). This study refines that understanding by showing how triggers in regulated systems are frequently governance-induced and operational rather than episodic or symbolic. The identified triggers did not introduce new tensions. Instead, they altered the conditions under which competing objectives could no longer be accommodated through routine practice.

The mechanism of activation can be stated more precisely than existing literature has allowed. Triggers operate by collapsing the institutional arrangements that maintain latency. Regulatory reform collapses temporal sequencing, while workload pressure removes organisational slack. Procedural demands collapse the discretionary space within which autonomy had been exercised. In each case, the trigger does not create a new contradiction but removes an arrangement that had kept an existing contradiction from becoming simultaneously actionable.

This is particularly visible in the interaction between the AIA and conformity assessment accountability. The AIA explicitly institutionalises a risk-based approach while requiring ongoing lifecycle risk management (Regulation (EU) 2024/1689, Recitals (6) and (65)). Such provisions align with the persistence of paradox since they anticipate continuous reassessment. When combined with MDR/IVDR reform and intensified oversight, this contributes to conditions under which regulatory professionals experience heightened constraint and hesitation, even when recognising potential efficiency gains from AI tools in their own assessment work. Salience therefore emerges as constrained action shaped by defensibility requirements, rather than overt conflict or explicit trade-off decisions as described in previous research (Power, 1997; Bardach and Kagan, 1982).

5.1 AI as a cross-cutting amplifier

The findings reveal that AI occupies a distinctive analytical position within the trigger-tension architecture. Unlike the identified triggers, each of which has a primary tension it activates, AI cross-cuts all five paradoxical tensions simultaneously. It promises efficiency gains in assessment work (sharpening the efficiency-quality tension), requires new expertise and learning routines (activating exploration-exploitation), demands collaboration with technology providers and manufacturers (activating collaboration-isolation), introduces new forms of autonomous decision support within assessment processes (activating autonomy-control) and raises questions about what counts as acceptable evidence for regulatory approval (sharpening protection-innovation).

This cross-cutting quality makes AI theoretically distinct from the triggers identified in this study. AI is not a trigger in the sense of a discrete change in governance conditions. Rather, it functions as an amplifying condition that lowers the threshold for activation across the system. Where regulatory reform might primarily activate the protection-innovation tension with secondary effects elsewhere, AI sharpens all tensions simultaneously, creating conditions under which multiple latent contradictions become salient at once. This resonates with paradox research on interconnected tensions (Smith and Lewis, 2011; Schad *et al.*, 2016) but extends it by identifying a specific mechanism, namely technological novelty within a multi-regime governance system, through which such interconnection occurs in practice.

The cross-cutting of AI acting as an amplifier is consistent with observations in AI governance scholarship. The AIA's reliance on conformity assessment as its primary enforcement mechanism places notified bodies at the centre of a regulatory instrument that, as Laux *et al.* (2024a) have shown, operates with a simplified understanding of trust. At the same time, the delegation of normative specification to standardisation bodies (Veale and Zuiderveen Borgesius, 2021; Laux *et al.*, 2024b) means that the practical resolution of competing requirements falls to the organisations performing assessment work. These dynamics reinforce the finding that AI does not introduce new tensions but intensifies existing ones by compressing the discretionary space within which regulatory professionals have managed contradiction.

For regulatory governance, this implies that AI adoption in conformity assessment cannot be understood as a single implementation challenge. It is a systemic amplifier that renders the entire architecture of designed paradox more fragile by simultaneously pressuring the arrangements that maintain latency across multiple tensions. This helps explain why the adoption of AI tools within regulatory assessment work often appears cautious or fragmented: the hesitation is not about AI per se but about the system-wide activation of contradictions that the regulatory architecture was designed to keep separate.

The findings contribute to regulatory governance scholarship by reframing paradox not as an emergent property of organisational complexity but as a deliberately authored feature of institutional architecture. Existing paradox theory generally treats contradictions as properties of organising that arise from the simultaneous pursuit of competing demands (Smith and Lewis, 2011; Schad *et al.*, 2016). From this perspective, paradoxes are discovered in organisational life and subsequently managed through cognitive, behavioural or structural responses. The present study suggests a different ontology for regulated settings: some contradictions are not discovered but authored. They are written into legal texts by institutional designers who codify competing objectives as parallel obligations with full awareness that they cannot be reconciled in practice. The MDR does not accidentally juxtapose safety and innovation; it deliberately articulates both as non-hierarchical objectives within the same legal instrument. Subsequent amendments do not resolve this tension; they preserve it by reaffirming both objectives under conditions of system strain.

This deliberate codification of contradiction distinguishes what we observe from the latent paradoxes described in existing theory. Hahn and Knight (2021) conceptualise latent paradoxes as potentialities embedded in socio-material arrangements. Our findings specify a more active mechanism: regulatory systems do not merely harbour contradictions as latent potentialities but deliberately construct and preserve them through legal codification, amendment and the layering of complementary regimes. We propose the concept of authored paradox to capture this distinction. Authored paradoxes are contradictions that are intentionally embedded in institutional design, maintained through governance arrangements and distributed across actors who are required to operationalise competing objectives without formal mechanisms for reconciliation.

The concept of authored paradox does not apply to all organisational contradictions. It is analytically specific to settings where competing objectives are explicitly codified in institutional texts, preserved through deliberate amendment and distributed across actors without mechanisms for reconciliation. This distinguishes authored paradox from emergent contradictions that arise through organisational growth, strategic drift or the collision of competing institutional logics (Greenwood *et al.*, 2011). It also distinguishes it from regulatory trade-offs, where decision-makers are expected to prioritise one objective over another. In authored paradox, no such prioritisation is sanctioned; both objectives are formally non-hierarchical, and the practical balancing is pushed downstream into professional work. The intentionality of authorship is inferred not from the subjective aims of legislators but from the observable pattern of codification, amendment and preservation: contradictions are written, rewritten and maintained across successive regulatory instruments.

The concept of authored paradox connects to Majone's (1994, 1997) account of the regulatory state. Majone argues that regulatory systems achieve legitimacy through credible commitment to multiple objectives simultaneously. Our finding extends this by identifying the mechanism through which credible commitment operates: the codification of contradiction.

The concept of authored paradox also has implications for how paradox theory conceptualises the relationship between institutional design and paradox dynamics. If contradictions can be deliberately authored and maintained, then the question shifts from "how do organisations cope with paradox?" to "who authors contradictions, for whom, and with what consequences for the distribution of responsibility?" This reframing aligns with recent calls to attend more seriously to the political dimensions of paradox (Putnam *et al.*, 2016).

This has direct implications for innovation theory. Existing explanations for why innovation stalls in regulated environments typically emphasise regulatory burden, compliance costs or institutional complexity as barriers to adoption (Greenwood *et al.*, 2011). These accounts treat contradiction as friction that impedes innovation. The present findings suggest a different mechanism: innovation does not stall because regulation creates obstacles but because regulatory architectures are designed to sustain contradictions that become simultaneously actionable when innovation pressures intensify. Authored paradox explains why incremental regulatory reform often fails to accelerate innovation. Reducing one requirement (for instance, streamlining documentation) does not resolve the underlying contradiction but merely shifts its expression elsewhere in the system, because both poles of the tension are codified as non-negotiable objectives. This reframes the challenge for innovation management: the question is not how to reduce regulatory friction but how to innovate within architectures that are designed to sustain it.

5.2 Implications for the governance of AI in conformity assessment

Practically, the findings suggest that policy ambitions to improve consistency, speed and rigour in conformity assessment may generate countervailing pressures when implemented

through intensified oversight and documentation demands. For regulators, this implies that introducing AI into conformity assessment requires governance arrangements that explicitly acknowledge the contradictions AI will activate, rather than treating adoption as a technical implementation task. Regulatory guidance that clarifies acceptable use, specifies how AI-supported assessments are to be documented, and delineates accountability between human judgement and algorithmic output would reduce the conditions under which AI use becomes informal and institutionally disowned.

For notified bodies, the findings point to the value of creating structured spaces for experimentation with AI tools within assessment work, insulated from immediate accreditation scrutiny, so that learning can occur without triggering the full weight of accountability arrangements. It should be noted that organisational sandboxes, that is protected spaces for organisational learning, are related to, but distinct from, the regulatory sandbox provisions established under Article 57 of the AIA (Regulation (EU) 2024/1689). AI regulatory sandboxes, as defined in the Act, provide controlled environments for testing innovative AI systems prior to market placement, primarily oriented towards providers and deployers of AI products (Veale and Zuiderveen Borgesius, 2021; Smuha, 2021). The structured spaces proposed here serve a different purpose: they are directed at regulatory professionals who need to develop competence and institutional routines for incorporating AI into assessment work itself. Where sandboxes address the question of how AI products enter the market, the spaces proposed here address how regulatory organisations learn to work with AI under conditions of accountability and procedural constraint. The distinction is important to note because the governance challenges identified in this study are primarily about the organisational and professional conditions under which AI can be legitimately adopted within regulatory practice as opposed to product validation.

For innovators operating within the medical device sector, the findings suggest that regulatory hesitation around AI is not resistance to technology but a systemic response to the activation of contradictions that the regulatory architecture was designed to keep separate. Understanding this dynamic may help innovators anticipate where delays will occur and design engagement strategies accordingly.

5.3 Limitations and future research

This study is limited to EU medical device governance and relies on a qualitative design focused on documents, interviews and observations. The first author's professional background in the regulatory field, while enabling access and depth of understanding, also introduces the risk that established assumptions may have shaped the identification and interpretation of tensions. While this risk was mitigated through reflexive practices and co-author discussion (see Section 3.3), it remains a limitation inherent to insider research of this kind.

Key stakeholders in the broader regulatory architecture, including manufacturers, national CAs, the European Commission, standards bodies and patient or civil-society representatives, are not included as informants. Their perspectives would be valuable for understanding how paradoxical tensions operate across the full regulatory system, and this constitutes a limitation of the study. However, the analytical objective here is to examine how tensions embedded in regulatory design are experienced and negotiated within the assessment function, rather than to provide a multi-actor account of the entire governance system. Future research could extend the analysis to these additional actors to examine whether and how the paradoxical dynamics identified here are perceived, contested or managed at other nodes within the regulatory architecture.

Future research could test whether the identified triggers operate similarly in other regulated domains where multiple regimes overlap. Comparative work could examine whether different regulatory architectures stabilise or activate tensions differently, and whether the same triggers produce different patterns of salience depending on enforcement intensity or organisational position.

Furthermore, comparative research could examine how different legal traditions and governance cultures author paradox differently, whether some architectures produce more durable latency than others and what happens when authored paradoxes accumulate across overlapping regimes.

6. Conclusions

This study set out to examine how paradoxical tensions are institutionally embedded within EU MDR (RQ1) and why they become salient during periods of regulatory change (RQ2).

Addressing RQ1, the findings show that contradiction is not incidental to regulation but built into its institutional design. EU MDR articulates multiple objectives that coexist without hierarchy, and successive regulatory reforms preserve these objectives rather than resolve their tensions. We conceptualise this as an authored paradox: contradictions that are intentionally codified in legal texts, maintained through governance arrangements and distributed across actors without formal mechanisms for reconciliation. Latency is sustained in everyday regulatory work through procedures, divisions of responsibility and professional norms that allow contradictory demands to remain unarticulated.

Addressing RQ2, paradoxical tensions become salient when regulatory conditions change in ways that disrupt stabilising arrangements. Four governance-induced triggers, namely regulatory reform, workload pressure, institutional scrutiny and procedural demands, collapse the arrangements that keep contradictions latent, rendering them simultaneously consequential for action. In this case, regulatory reform also operated as a meta-trigger, conditioning the intensity of the other three triggers through the expanded scope and accountability requirements of the MDR and IVDR. Across these triggers, AI functioned as a cross-cutting amplifier that sharpened all five tensions simultaneously.

By locating paradox dynamics in legal frameworks and governance arrangements, this study contributes to innovation and regulation research by shifting attention away from individual perceptions of tension towards institutional conditions of action. It shows how regulatory systems are designed to operate under contradiction and how change within those systems affects the viability of routine work. For innovation research, the findings help explain why emerging technologies such as AI become contentious not because of their technical novelty alone but because they intersect with existing regulatory tensions around accountability, discretion and control.

The study has implications beyond the medical device sector, as many innovation domains are governed by regulatory systems that stabilise contradiction through similar institutional architectures, suggesting that the dynamics identified here may help explain why governance responses to emerging technologies often appear cautious or fragmented.

Author contributions

All authors designed the study. Ingela Mauritzon conducted the data collection and drafted the manuscript. All authors contributed to the writing, conceptual framing and analysis.

Ethical approval

Participants were informed of the purpose of the study and consented to be interviewed. No identifiable personal data are included in the study.

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Appendix 1

Interview guide

The interviews followed a semi-structured format organised around three thematic areas. Within each area, one or two opening questions are used to initiate discussion, followed by flexible probing depending on the participant's responses.

This guide is designed to elicit detailed accounts of *everyday regulatory work and experiences of change* rather than to impose predefined categories or theoretical language.

1. Professional role and conformity assessment practice

- Tell me about how you came to work in this industry?
- Can you describe your current role and how do you engage with conformity assessment on a day-to-day basis?
- Can you describe your work and your professional tasks?
- Who do you interact with professionally in your work?

Probes: responsibilities, types of assessments, nature of interaction with manufacturers and colleagues and industry, coordination with colleagues or external actors.

2. Regulatory change and the transition to MDR/IVDR

- How has your work changed since the introduction of the MDR/IVDR?
- Can you describe a situation where the new requirements created difficulties or uncertainty in your assessment work?

Probes: documentation demands, accountability expectations, relationships with competent authorities, experiences of disruption or adjustment.

3. AI and evolving assessment practices

- Have you encountered AI either as something you assess in devices or as something that could be used in your own assessment work?
- How do you see the AI Act affecting conformity assessment going forward?
- How do you see your company implementing AI going forward?
- What do you think the future is for AI in conformity assessment?

Probes: perceptions of AI tools, concerns about competence or readiness, expectations about future changes, views on guidance or standardisation.

Closing

(1) Is there anything we haven't discussed that you think is important for understanding the challenges facing conformity assessment today?

Appendix 2

Table A1. Cross-cutting trigger-tension analysis

Trigger	Tension activated	Empirical manifestation	Illustrative evidence	Section
Regulatory reform (MDR/IVDR implementation)	Protection and safety ↔ Innovation and access (primary)	Expanded documentation, stricter audit regimes and procedural accountability redirected attention towards compliance and defensibility, narrowing perceived space for innovation within NB work	"The auditing role focuses on compliance, not fostering innovation. Even though that is why I took this job in the first place, to bring innovation to market" (n2)	4.5
	Exploration ↔ Exploitation (secondary)	Expanded regulatory scope increased procedural rigidity, reducing capacity for exploratory learning within established assessment routines	Informal AI experimentation occurred alongside formal prohibition, indicating constrained exploration under expanded compliance requirements	4.5, 4.6
	Autonomy ↔ Control (secondary)	New procedural layers introduced by regulatory reform added approval requirements that reduced scope for discretionary professional judgement	Withdrawal of accreditation and loss of employment described as persistent threats reinforcing compliance orientation over professional discretion	4.5, 4.9
Workload and resource pressure	Exploration ↔ Exploitation (primary)	Increased assessment volumes and complexity under constrained staffing narrowed space for exploratory learning and experimentation with new technologies	"We should use AI, but that would mean getting everyone on board, and it's just too much . . . We don't have time for that right now" (n10)	4.6
	Efficiency ↔ Quality (secondary)	Rising volumes intensified pressure to maintain throughput, exposing gaps between formally defined quality standards and the conditions required to sustain them	"We are putting the buckets out for the leaky roof without fixing the hole" (n17)	4.6, 4.8
	Autonomy ↔ Control (secondary)	Time scarcity reduced opportunities for discretionary judgement, as professionals defaulted to standardised routines under pressure	Capacity constraints described as forcing reliance on existing SOPs, even when professional judgement suggested alternative approaches	4.6, 4.9

(*continued*)

Table A1. Continued

Trigger	Tension activated	Empirical manifestation	Illustrative evidence	Section
Heightened institutional scrutiny	Collaboration ↔ Isolation (primary)	Intensified oversight from designating authorities reframed collaboration with manufacturers as a professional risk rather than a procedural norm	"We're not allowed to speak to our clients. As a former R&D engineer, this is frustrating because I know I could help" (n1)	4.7
	Efficiency ↔ Quality (secondary)	Heightened defensibility demands increased justification work, adding to documentation burden without corresponding efficiency gains	Cautious language and partial disclosures observed at industry events reflected scrutiny-induced constraints on open professional exchange	4.7, 4.8
	Autonomy ↔ Control (secondary)	External oversight intensified internal formalisation, as organisations sought to demonstrate compliance through expanded approval layers	Scrutiny from designating authorities described as reinforcing internal control mechanisms that further constrained professional discretion	4.7, 4.9
Procedural and organisational demands	Efficiency ↔ Quality (primary)	Increasing documentation and reporting obligations transformed previously compatible goals into a persistent source of moral strain	"There's a constant moral dilemma in balancing quality with deadlines" (n9)	4.8
	Autonomy ↔ Control (primary)	Expanded approval layers and performance monitoring reduced professional discretion, transforming autonomy from taken-for-granted to an explicit object of concern	"We used to rely on professional judgement; now every deviation needs formal approval" (n4)	4.9
	Protection ↔ Innovation (secondary)	Compliance-oriented procedural demands reinforced safety and traceability logics, further narrowing perceived space for innovation	Procedural definitions of quality constrained AI use even when recognised as a potential means of improving consistency	4.8, 4.5

Note(s): This table maps each trigger to the paradoxical tensions it activates, distinguishing primary from secondary activation, and provides empirical manifestations, illustrative evidence and corresponding findings sections. This complements Table 2 (which documents how tensions are embedded in legal texts) by showing how and where they become salient in regulatory practice

AI as cross-cutting amplifier

Across all four triggers, the increasing presence of AI in conformity assessment work functioned as an amplifying condition. AI sharpened existing contradictions by simultaneously representing a potential solution to capacity and consistency pressures and a source of heightened accountability, legitimacy and procedural risk. AI did not constitute a standalone trigger but intensified the salience of all five paradoxical tensions when combined with regulatory reform, workload pressure, institutional scrutiny or procedural demands.

Source(s): Authors' own work

References

Alvesson, M. and Sköldberg, K. (2018), *Reflexive Methodology: New Vistas for Qualitative Research*, 3rd ed., Sage, London.

Andriopoulos, C. and Lewis, M.W. (2009), "Exploitation-exploration tensions and organizational ambidexterity: managing paradoxes of innovation", *Organization Science*, Vol. 20 No. 4, pp. 696-717, doi: 10.1287/orsc.1080.0406.

Baldwin, R. and Cave, M. (1999), *Understanding Regulation: Theory, Strategy, and Practice*, Oxford University Press, Oxford.

Bardach, E. and Kagan, R.A. (1982), *Going by the Book: the Problem of Regulatory Unreasonableness*, Temple University Press, Philadelphia, PA.

Benson, J.K. (1977), "Organizations: a dialectical view", *Administrative Science Quarterly*, Vol. 22 No. 1, pp. 1-21, doi: 10.2307/2391741.

Braithwaite, J. and Drahos, P. (2000), *Global Business Regulation*, Cambridge University Press, Cambridge.

Cameron, K.S. and Quinn, R.E. (1988), "Organizational paradox and transformation", in Quinn, R.E. and Cameron, K.S. (Eds), *Paradox and Transformation: toward a Theory of Change in Organization and Management*, Ballinger, Cambridge, MA, pp. 1-18.

Creswell, J.W. (2013), *Qualitative Inquiry and Research Design: Choosing Among Five Approaches*, 3rd ed., Sage, Thousand Oaks, CA.

Czarniawska, B. (2004), *Narratives in Social Science Research*, Sage, London.

Dubois, A. and Gadde, L.-E. (2002), "Systematic combining: an abductive approach to case research", *Journal of Business Research*, Vol. 55 No. 7, pp. 553-560, doi: 10.1016/s0148-2963(00)00195-8.

Farjoun, M. (2010), "Beyond dualism: stability and change as a duality", *Academy of Management Review*, Vol. 35 No. 2, pp. 202-225, doi: 10.5465/amr.2010.48463331.

Floridi, L. (2021), "The European legislation on AI: a brief analysis of its philosophical approach", *Philosophy and Technology*, Vol. 34 No. 2, pp. 215-222, doi: 10.1007/s13347-021-00460-9.

Gilbert, S., Anderson, S., Daumer, M., Li, P., Melvin, T. and Williams, R. (2023), "Learning from experience and finding the right balance in the governance of artificial intelligence and digital health technologies", *Journal of Medical Internet Research*, Vol. 25, e43682, doi: 10.2196/43682.

Greenwood, R., Raynard, M., Kodeih, F., Micelotta, E.R. and Lounsbury, M. (2011), "Institutional complexity and organizational responses", *Academy of Management Annals*, Vol. 5 No. 1, pp. 317-371, doi: 10.5465/19416520.2011.590299.

Hahn, T. and Knight, E. (2021), "The ontology of organizational paradox: a quantum approach", *Academy of Management Review*, Vol. 46 No. 2, pp. 362-384, doi: 10.5465/amr.2018.0408.

Han, Y., Ceross, A. and Bergmann, J. (2024), "Regulatory frameworks for AI-enabled medical device software in China: comparative analysis and review of implications for global manufacturer", *JMIR AI*, Vol. 3, e46871, doi: 10.2196/46871.

Hood, C., Rothstein, H. and Baldwin, R. (2001), *The Government of Risk: Understanding Risk Regulation Regimes*, Oxford University Press, Oxford.

Jarzabkowski, P., Lê, J.K. and Van de Ven, A.H. (2013a), "Responding to competing strategic demands: how organizing, belonging, and performing paradoxes coevolve", *Strategic Organization*, Vol. 11 No. 3, pp. 245-280, doi: 10.1177/1476127013481016.

Jarzabkowski, P., Smets, M., Bednarek, R., Burke, G. and Spee, P. (2013b), "Institutional ambidexterity: leveraging institutional complexity in practice", in Lounsbury, M. and Boxenbaum, E. (Eds), *Institutional Logics in Action, Part B*, Emerald, Bingley.

Jordana, J. and Levi-Faur, D. (2004), "The politics of regulation in the age of governance", in Jordana, J. and Levi-Faur, D. (Eds), *The Politics of Regulation: Institutions and Regulatory Reforms for the Age of Governance*, Edward Elgar, Cheltenham, pp. 1-28.

Kerwin, C.M. (2003), *Rulemaking: How Government Agencies Write Law and Make Policy*, 3rd ed., CQ Press, Washington, DC.

Laux, J., Wachter, S. and Mittelstadt, B. (2024a), "Trustworthy artificial intelligence and the European Union AI Act: on the conflation of trustworthiness and acceptability of risk", *Regulation and Governance*, Vol. 18 No. 1, pp. 3-32, doi: 10.1111/rego.12512.

Laux, J., Wachter, S. and Mittelstadt, B. (2024b), "Three pathways for standardisation and ethical disclosure by default under the European Union Artificial Intelligence Act", *Computer Law and Security Review*, Vol. 53, 105957, doi: 10.1016/j.clsr.2024.105957.

Levi-Faur, D. (2005), "The global diffusion of regulatory capitalism", *Annals of the American Academy of Political and Social Science*, Vol. 598 No. 1, pp. 12-32, doi: 10.1177/0002716204272371.

Levi-Faur, D. (2012), "From 'big government' to 'big governance'", in Levi-Faur, D. (Ed.), *The Oxford Handbook of Governance*, Oxford University Press, Oxford, pp. 3-18.

Levinthal, D.A. and March, J.G. (1993), "The myopia of learning", *Strategic Management Journal*, Vol. 14 No. S2, pp. 95-107, doi: 10.1002/smj.4250141009.

Lewis, M.W. (2000), "Exploring paradox: toward a more comprehensive guide", *Academy of Management Review*, Vol. 25 No. 4, pp. 760-776, doi: 10.2307/259204.

Li, H., He, X., Subbaswamy, A., Vossler, P., Gossmann, A., Singh, K. and Feng, J. (2026), "Scaling medical device regulatory science using large language models", *Npj Digital Medicine*, Vol. 9 No. 1, p. 221, doi: 10.1038/s41746-026-02353-7.

Lincoln, Y.S. and Guba, E.G. (1985), *Naturalistic Inquiry*, Sage, Newbury Park, CA.

Luckner, S. and Lauer, W. (2025), "Regulatory classification of AI-enabled products for medical use on the basis of the EU AI Act and MDR/IVDR", *Bundesgesundheitsblatt*, Vol. 68 No. 8, pp. 854-861.

Majone, G. (1994), "The rise of the regulatory state in Europe", *West European Politics*, Vol. 17 No. 3, pp. 77-101.

Majone, G. (1997), "From the positive to the regulatory state: causes and consequences of changes in the mode of governance", *Journal of Public Policy*, Vol. 17 No. 2, pp. 139-167, doi: 10.1017/s0143814x00003524.

March, J.G. (1991), "Exploration and exploitation in organizational learning", *Organization Science*, Vol. 2 No. 1, pp. 71-87, doi: 10.1287/orsc.2.1.71.

Mauritzon, I. and Guo, Y. (2026), "Artificial intelligence in medical device conformity assessment and regulatory governance: a systematic evidence map", *Chinese Journal of Medicine Guide*, in press.

Moran, M. (2003), *The British Regulatory State: High Modernism and Hyper-Innovation*, Oxford University Press, Oxford.

Page, E.C. (2001), *Governing by Numbers: Delegated Legislation and Everyday Policymaking*, Hart Publishing, Oxford.

Palma Ortigosa, A. (2024), *Who is who in the Artificial Intelligence Act? the Notifying Authorities and Notified Bodies*, Actualidad Juridica Iberoamericana, No. 21, pp. 598-617.

Poole, M.S. and Van de Ven, A.H. (1989), "Using paradox to build management and organization theories", *Academy of Management Review*, Vol. 14 No. 4, pp. 562-578, doi: 10.2307/258559.

Power, M. (1997), *The Audit Society: Rituals of Verification*, Oxford University Press, Oxford.

Power, M. (1999), "The audit society: second thoughts", *International Journal of Auditing*, Vol. 3 No. 3, pp. 169-178.

Putnam, L.L., Fairhurst, G.T. and Banghart, S. (2016), "Contradictions, dialectics, and paradoxes in organizations: a constitutive approach", *Academy of Management Annals*, Vol. 10 No. 1, pp. 65-171, doi: 10.5465/19416520.2016.1162421.

Raisch, S. and Birkinshaw, J. (2008), "Organizational ambidexterity: antecedents, outcomes, and moderators", *Journal of Management*, Vol. 34 No. 3, pp. 375-409, doi: 10.1177/0149206308316058.

Raisch, S., Hargrave, T.J. and Van de Ven, A.H. (2018), "The learning spiral: a process perspective on paradox", *Journal of Management Studies*, Vol. 55 No. 8, pp. 1507-1526, doi: 10.1111/joms.12397.

Reichertz, J. (2014), "Induction, deduction, abduction", in Flick, U. (Ed.), *The SAGE Handbook of Qualitative Data Analysis*, Sage, London, pp. 123-135.

Schad, J. and Bansal, P. (2018), "Seeing the forest and the trees: how a systems perspective informs paradox research", *Academy of Management Review*, Vol. 43 No. 4, pp. 726-745.

Schad, J., Lewis, M.W., Raisch, S. and Smith, W.K. (2016), "Paradox research in management science: looking back to move forward", *Academy of Management Annals*, Vol. 10 No. 1, pp. 5-64, doi: 10.5465/19416520.2016.1162422.

Schmidt, J., Schutte, N.M., Buttigieg, S., Novillo-Ortiz, D., Sutherland, E., Anderson, M., de Witte, B., Peolsson, M., Unim, B., Pavlova, M., Stern, A.D., Mossialos, E. and van Kessel, R. (2024), "Mapping the regulatory landscape for artificial intelligence in health within the European Union", *Npj Digital Medicine*, Vol. 7 No. 1, p. 229, doi: 10.1038/s41746-024-01221-6.

Scott, W.R. (2001), *Institutions and Organizations*, 2nd ed., Sage, Thousand Oaks, CA.

Scott, C. (2004), "Regulation in the age of governance: the rise of the post-regulatory state", in Jordana, J. and Levi-Faur, D. (Eds), *The Politics of Regulation*, Edward Elgar, Cheltenham, pp. 145-174.

Smith, W.K. and Lewis, M.W. (2011), "Toward a theory of paradox: a dynamic equilibrium model of organizing", *Academy of Management Review*, Vol. 36 No. 2, pp. 381-403, doi: 10.5465/amr.2009.0223.

Smuha, N.A. (2021), "From a 'race to AI' to a 'race to AI regulation': regulatory competition for artificial intelligence", *Law, Innovation and Technology*, Vol. 13 No. 1, pp. 57-84, doi: 10.1080/17579961.2021.1898300.

Tushman, M.L. and O'Reilly, C.A. (1996), "Ambidextrous organizations: managing evolutionary and revolutionary change", *California Management Review*, Vol. 38 No. 4, pp. 8-30, doi: 10.2307/41165852.

Veale, M. and Zuiderveen Borgesius, F. (2021), "Demystifying the draft EU Artificial Intelligence Act", *Computer Law Review International*, Vol. 22 No. 4, pp. 97-112.

Vogel, D. (1996), *National Styles of Regulation: Environmental Policy in Great Britain and the United States*, Cornell University Press, Ithaca, NY.

Zhou, K. and Gattinger, G. (2024), "The evolving regulatory paradigm of AI in MedTech: a review of perspectives and where we are today", *Therapeutic Innovation and Regulatory Science*, Vol. 58 No. 3, pp. 456-464, doi: 10.1007/s43441-024-00628-3.

Legal and policy sources (EU)

European Commission (2026), "NANDO – new approach notified and designated organisations information system", available at: https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies.

European Parliament and Council of the European Union (2017a), "Regulation (EU) 2017/745 on medical devices", *Official Journal of the European Union, L 117*, pp. 1-175.

European Parliament and Council of the European Union (2017b), "Regulation (EU) 2017/746 on in vitro diagnostic medical devices", *Official Journal of the European Union, L 117*, pp. 176-332.

Further reading

European Parliament and Council of the European Union (2016), "Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data (General Data Protection Regulation)", *Official Journal of the European Union, L 119*, pp. 1-88.

European Parliament and Council of the European Union (2023), "Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards transitional provisions", *Official Journal of the European Union, L 80*, pp. 24-27.

European Parliament and Council of the European Union (2024), "Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act)", *Official Journal of the European Union, L*, 2024/1689, 12 July 2024.

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