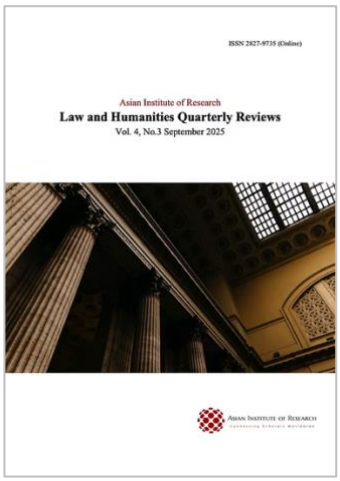

Law and Humanities Quarterly Reviews

Nweke, G. I., Nweke, O. C., & Mocha, S. C. (2025). Balancing Innovation and Oversight: A Document Analysis of Regulatory Compliance Frameworks. *Law and Humanities Quarterly Reviews*, 4(3), 47-56.

ISSN 2827-9735

DOI: 10.31014/aior.1996.04.03.154

The online version of this article can be found at:
https://www.asianinstituteofresearch.org/

Published by:
The Asian Institute of Research

The Asian Institute of Research Law and Humanities Quarterly Reviews is a peer-reviewed International Journal of the Asian Institute of Research. The journal covers scholarly articles in the interdisciplinary fields of law and humanities, including constitutional and administrative law, criminal law, civil law, international law, linguistics, history, literature, performing art, philosophy, religion, visual arts, anthropology, culture, and ethics studies. The Law and Humanities Quarterly Reviews is an Open Access Journal that can be accessed and downloaded online for free. Thus, ensuring high visibility and increase of citations for all research articles published. The journal aims to facilitate scholarly work on recent theoretical and practical aspects of law.

ASIAN INSTITUTE OF RESEARCH
Connecting Scholars Worldwide

The Asian Institute of Research
Law and Humanities Quarterly Reviews
Vol.4, No.3, 2025: 47-56
ISSN 2827-9735

DOI: 10.31014/aior.1996.04.03.154

Balancing Innovation and Oversight: A Document Analysis of Regulatory Compliance Frameworks

Gordian I. Nweke[1], Ogochukwu C. Nweke[2], Samuel C Mocha[3]

[1] Faculty of Business Management, Capella University, Minneapolis, MN, USA
[2] School of Business, Leadership and Legal Studies (SBLL), Regent University College of Science and Technology, Accra, Ghana
[3] Assistant Professor, CoBM, Colorado Technical University

Correspondence: Ogochukwu C. Nweke. Email: bravellb@gmail.com

Abstract
Regulatory compliance frameworks provide the mechanism to ensure that innovations adhere to ethical standards and enhance the safety of individuals. However, regulatory frameworks can also stifle innovations if they become too strict. This study, therefore, reviews and compares the innovation regulatory frameworks to ascertain how developed and developing countries balance the promotion of health innovations with the need to enhance public safety and ethical standards in the health industry. The study adopted the qualitative documentary analysis approach and analyzed eight regulatory frameworks from the USA, the UK, the European Union, and Sub-Saharan Africa (SSA). The thematic analysis in analyzing the data guided by four regulatory theories. The findings of the study were discussed under four emerging themes, guided by four regulatory theories. The themes included risk-based stratification, adaptive frameworks, transparency and ethics, and regulatory compliance. The findings showed that regulatory frameworks of developed economies are characterized by high-risk-based stratification regimes, adaptive systems, transparency, and coordinating regulatory systems that constitute an innovation-enabling framework with assured patient security and public confidence. On the contrary, the health regulatory environment in SSA is still under development and is marked by irregular regulation, low capacity, and an increasing focus on regional harmonization through frameworks. Regulatory bodies and decision-makers in SSA can learn from the successful mechanisms of developed countries and tailor their strategies to local realities. This can ensure that innovations in health are not merely effective and safe but also accessible to those who most need them.

Keywords: Health Innovations, Regulatory Compliance, Regulatory Framework, Regulatory Theories, Risk-Based Regulatory

1. Introduction

Innovation is widely recognized by industry and academics as an essential competitive enabler for any enterprise that wants to remain competitive and survive, and grow. Innovation is the efforts of individuals to introduce and execute new and useful ideas, products, processes, or methods in their function, group, or organization (Carr et al.,

2016). The concepts of innovation do not only stress the generation of new ideas but also their execution to achieve and trigger creativity. Meglio and Di Paola (2021) believe that innovation is essential for the sustenance and profitability of any organization, as well as societies and nations. Innovation enables organizations and societies to provide solutions to challenges, enhance the productivity and well-being of individuals. According to Scott and Bruce (1994), innovation encompasses three important steps: firstly, finding the problems and developing innovative solutions; secondly, finding support and agreement from other people within the workplace or company; and thirdly, formulating and testing a prototype or model that can be implemented within the company or workplace. Lu et al. (2008) differentiate between two broad categories of innovation: incremental and radical. Incremental innovation focuses on improving existing systems by identifying and fixing weaknesses—this is often called continuous improvement. In contrast, radical innovation involves creating and using entirely new methods to significantly improve how things are done within an organization (Salerno et al., 2025).

Innovation is encouraged across all industries and facets of society due to its ability to enhance performance and improve overall outcomes. The health sector is among the major industries that have witnessed the proliferation of innovation within the last two decades. According to the World Health Organization (WHO), as cited in Omachonu and Einspruch (2010), health innovation is defined as the introduction of new or improved health practices, procedures, systems, products and technology, services, and delivery methods that lead to better healthcare. The emerging innovations have transformed the sector to a great extent, altering the healthcare landscape and providing new avenues for enhancing patient outcomes and care. For instance, the application of digital health records is one of the major innovations in the healthcare sector (Kim et al., 2019). Kim et al. (2019) noted that electronic health records (EHRs) have replaced the traditional paper-based systems and enabled healthcare practitioners to save, manipulate, and retrieve patient data more efficiently. The application of EHRs gives health staff an easier way to share information, thus enhancing care coordination and continuity. They also provide the chance to analyze data and manage population health, therefore informing better decisions on what to do at any given moment (Seymour et al., 2012). Further, diagnosing diseases by Artificial Intelligence (AI) represents a significant innovation in the health sector. AI diagnostic tools enable physicians to diagnose swiftly and accurately through machine learning algorithms by processing vast amounts of data (Aamir et al., 2024). The tools improve diagnosis in the sense that they identify any possible threats or abnormalities, interpret medical images, and recognize patterns. To put it simply, the health innovation maximizes the performance of the health system to better fulfill the demands and needs of both the public and private healthcare. As noted by Islam (2021), healthcare Innovations improve treatment, diagnosis, education, outreach, prevention, research quality and delivery, and access to healthcare.

The foregoing shows that the importance of health innovation cannot be overemphasized; however, it may have its challenges if not regulated. Pham (2025) argued that innovation in the health industry may impede patients' safety, promote inequality, and breach ethical standards. Consequently, achieving a balance between innovation and patient safety, as well as enhancing ethical standards, is considered a significant policy and practice challenge in health systems. To maintain this balance, regions and countries have developed measures and regulatory compliance frameworks that guide health innovation. Regulatory compliance frameworks in the instance of health innovations form the pillars of governance, influencing the development, testing, approval, and roll-out of new interventions and technologies (Alex-Omiogbemi et al., 2024). Such frameworks encompass grand-scale mechanisms like licensing protocols, risk management systems, post-market surveillance, and enforcement measures (Rodriguez-Manzano et al., 2024). For example, the European Union has established the Medical Device Regulation (MDR – 2017/745), which regulates the European Union on the clinical investigation and placing on the market of medical devices for human use (Vasiljeva et al., 2020). Also, the Food and Drug Administration of the USA provides guidelines that regulate manufacturers on the development and approval of Software as a Medical Device (Carroll and Richardson, 2016).

This study argues that understanding how regulatory frameworks influence innovation and oversight in the health industry is most essential following recent global health catastrophes, like the COVID-19 pandemic. The emergence of the COVID-19 pandemic fueled innovation and deployment of new technology while revealing gaps and deficiencies in regulation (Elden et al., 2023). The expedited vaccine deployment, widespread implementation of digital health technologies, and artificial intelligence-driven clinical decision-making have once again

underscored the need for risk-based, adaptive regulatory systems with the capacity to evolve to meet changing public health demands in parallel with technological innovation (Aamir et al., 2024; Kim et al., 2019). Against this background, it is imperative to analyze how prevailing regulatory and compliance frameworks regulate the fine balance between compliance and innovation. This is because while their primary objective is to protect public health, these frameworks also play a pivotal role in shaping the innovation ecosystem by either facilitating or hindering the adoption of new solutions. Ranchordás (2024) asserted that overly stringent regulations may stifle innovation and limit patient access to beneficial technologies, whereas overly permissive frameworks may expose patients to unproven or unsafe interventions. Hence, finding the appropriate balance is significant so that the potential of health innovation can be transformed while keeping public confidence and safety above board.

It is from this background that this study seeks to analyze regulatory compliance frameworks of health innovations between developed societies (i.e., the USA, European Union, and the UK) and developing countries in Africa. The concentration on health innovations enables the research to fill a significant area of knowledge void in the current literature. The findings are helpful to regulators, policymakers, and health technology developers in designing and implementing regulatory frameworks that motivate innovation and adequately safeguard public health.

2. Theoretical Framework

This review is conducted within the regulatory theory framework. Regulatory theory provides a theoretical framework to understand how and why governments and regulatory bodies intervene in markets and social systems to manage risk, protect the public, and promote ethical standards (Ugochukwu, 2001). Regulatory theories essentially examine the basis for regulation, design, and the enforcement process, and adaptive regulatory discourse between regulators and entities that are being regulated (Drahos, 2017). This review uses regulatory theories to analyze how regulatory and compliance frameworks balance innovation with effective oversight in the health industry. Four regulatory theories – public interest, public choice, theory of responsive regulation, and risk-based regulation – provide the framework for this study.

Traditionally, an implicit assumption of the public interest theory is that regulation is, in the main, aimed at protecting the public. Public interest theory explains that regulation is the response to market failure — i.e., externality, information asymmetry, and monopolistic conduct — to serve the public interest and provide fairness, efficiency, and safety (Hantke-Domas, 2003). This research applies this paradigm to analyze why health regulatory frameworks are instituted in the first instance and how they attempt to further societal objectives, where innovation can bring new risks or uncertainties. Public choice theory presents an alternative, and sometimes more pessimistic, perspective in the form that regulatory systems could be influenced by vested interests of powerful stakeholders. Proponents of this theory argue that people in their political behavior cannot be assumed to be motivated by fundamentally different forces than in their private choice-making behavior. Self-interest is usually put above all other interests (Ugochukwu, 2001). The public choice theory assumes that stakeholders or policymakers may resort to regulatory capture to make decisions not necessarily optimal for the public good in general but for self-interest (Shaw, 2003). The public choice theory is used in this study to offer a critical analysis of regulatory frameworks and demand methods that facilitate increased transparency, accountability, and stakeholder engagement. Theory of responsive regulation proposes that regulatory frameworks should be flexible or respond to emerging demands (Heydon et al., 2024). This theory holds that regulation does not necessarily imply tough enforcement but partnership, guidance, and responsiveness (Heydon et al., 2024). This study applies these assumptions to examine how innovation regulation frameworks incorporate graduated mechanisms of enforcement, induce compliance through guidance, and cultivate cooperative relationships that allow for innovation while still exercising control. Risk-based regulation promotes prioritizing regulatory effort and focus according to risk of harm and severity of harm so that the regulation is proportionate and not needlessly prohibitive to innovation (Black and Baldwin, 2010).

Based on these multifaceted but interlinked regulatory theories, this research critically explores how structures of regulatory compliance are designed and implemented to attain an adequate equilibrium between promoting innovation and efficient regulation. This theoretical foundation informed the selection of documents, coding, and explanation of analytic themes in this research.

3. Empirical Review

The review of literature brings out a conflict between promoting health innovation and governing innovation in the healthcare sector. Lipworth et al. (2021) bring out the issue of how, despite being very valuable and highly esteemed, health innovation is typically not very well backed by evidence supporting its effectiveness and may be harmful to patients. They contend that firm regulation is required to safeguard patients against harm and exploitation by clinicians who hold vested interests in innovative practices. Gupta et al. (2018) extrapolate this problem to surgical innovation and reason that current oversight is ad hoc and disproportionate, and that this poses ethical hazards for both surgeons and patients. They put forward a structured, risk-based approach that targets oversight at the specific ethical challenges presented by various innovations. Paracha (2023) broadens the conversation beyond a single generation of emerging technologies like AI and big data platforms, and highlights cross-border complexities, resource limitations, and definitional uncertainties as significant barriers to successful regulation. Paracha posits that strategic clarity, stakeholder inclusivity, and an exquisite balance between innovation and accountability are essential to enabling innovation while ensuring trust and safety. Similarly, Kirklin (2021) writes of the close regulatory environment that orbits mechanical circulatory support (MCS), cautioning against overregulation of an area that can suffocate, particularly the development of technology for the pediatric patient. Krouse (2015) raises concerns of inadequate evidence and a lack of ethical control in deploying new medical interventions and devices. Krouse (2015) recommended open informed consent and participation of patients and disapproved unreviewed off-label utilization of devices. Wiersma et al. (2023) refer that health innovation is constantly changing and is uncontrollable, and it is characterized by overlap and inconsistency of control. They suggest counterbalancing the effort with a capacity to accept the exceptional cases and harmonizing monitoring systems across specialties.

Collectively, the studies illustrate that although innovation is at the heart of advancement in medicine and technology, it too often meets a disintegrated and at times incomplete system of regulation. Throughout all the studies, there is a unifying thread of requiring systems to achieve a balance between innovation, patient safety, ethics, and accountability, and it is achieved through open procedures, stakeholder involvement, and flexible, risk-based approaches to regulation.

The reviews present a shared identification of the persistent issues with aligning innovation with good regulation across all aspects of health and technological innovation. These findings highlight the urgent need for a thoughtful analysis of compliance regulatory architectures to examine how they balance enabling innovation with practicing rigorous regulation. Based on the findings of these reviewed studies, this review then tries to fill this gap by conducting a document analysis of regulatory compliance frameworks. This study aims to provide insightful knowledge on how regulatory frameworks can be made innovation-friendly and robust in protecting stakeholders by examining how these existing frameworks incorporate risk-based approaches, adaptive approaches, transparency, and ethics.

4. Methodology

This research utilizes qualitative document analysis (Morgan, 2022) to examine how regulatory regimes and compliance measures in the healthcare sector reconcile the dynamic tension between facilitating innovation and exercising proper oversight. Document analysis was appropriate in this review since it offers a solid and flexible research method that makes researchers focus on analyzing publicly available documents carefully (Bowen, 2009). The qualitative document analysis these researchers to identify the most significant findings, meanings, and trends in contemporary regulatory frameworks that guide health innovations.

The review employed an exploratory and interpretative design. This research aims to unveil how various regulatory compliance frameworks are constructed to facilitate and control innovation to protect the integrity of the health industry and the public good. Using an exploratory and interpretive approach is the right one here as the research seeks to learn and understand how various regulatory compliance systems are organized to enable innovation and also to govern (Orina et al., 2015). A design based on the exploratory approach was selected based on the understanding that regulatory systems are complicated and context-sensitive.

The researchers purposively chose available health regulatory compliance documents from open sources. These were international and national regulatory policies and guidelines, for example, those offered by the European Union, the United Kingdom (UK), the United States of America (USA), and the African Union. These documents were obtained from publicly available online repositories, the websites of regulatory agencies, and academic databases such as JSTOR, SSRN, and Google Scholar. The health regulatory frameworks analyzed in this study include Medical Device Regulation (MDR 2017/745) and the *Question-and-answer guidance of the MDR of the European Union. The review also analyzed the* Software as a Medical Device (SaMD) and Artificial Intelligence/Machine Learning (AI/ML) Action Plan – health innovation frameworks provided by the Food and Drug Administration of the USA. Focusing on the UK, the review analyzed the Digital Mental Health Technology (DMHT) guidance and Machine Learning (ML) Transparency Guidelines by the Medicines and Healthcare products Regulatory Agency (MHRA). Also, the study analyzed documents from the Sub-Saharan Africa (SSA) regions. The regulatory document from SSA includes the African Medicine Regulation Harmonization (AMRH) framework and the African Medicine Agency (AMA) framework.

This study used thematic analysis. According to Braun and Clarke (2006) six-phase methodology of analysis, the process began with familiarization through multiple readings of the documents. Emergent codes were established that highlighted salient features like risk-based regulatory styles, adaptive governance, and collaborative monitoring forms. Codes were then grouped into broad themes to identify lasting patterns and conceptual associations identified in regulation schemes. Themes were further exemplified and explained about the whole dataset for them to capture the essence of the documents and their subtlety in showing interaction between compliance and innovation. In the final steps, themes were labeled and operationalized to give more emphasis on their meaning and effects within the regulatory environment; a narrative synthesis was developed with illustrative quotes and passages from the documents to give punctuation to interpretation.

To ensure the credibility and validity of the research, triangulation was used in comparing opinions within and across different documents and sources of varying types. Decision analysis for the procedure in coding and why themes were constructed was preserved in the audit trail to ensure maximum transparency and reliability. Peer debriefing of seasoned colleagues doing work in regulatory studies was conducted to scrutinize interpretation, to reduce possible researcher bias, and to increase the credibility of the findings. No formal ethical approvals were required for this research study because the data collection process was not based on human subjects but on publicly available documents. However, appropriate ethical standards were maintained in the shape of rightful source attribution and respect for intellectual property, and regulation of copyright.

5. Findings

The review identified four main themes from the review of regulatory compliance frameworks from the EU, USA, UK, and SSA. The themes included risk-based stratification, adaptive frameworks, transparency and ethics, and regulatory compliance. The themes have been presented in Table 1.

Table 1: Comparison of emerging themes

Aspect	EU	USA	UK	SSA
Risk-based stratification	Detailed class system, lifecycle & UDI oversight	IMDRF risk classes for SaMD, including quality systems	Classifies DMHT risk I–III, clear diagnostic distinctions	Less formal classification; pilot reliance frameworks emerging
Adaptive frameworks	Post-market feedback with real-world data review	AI/ML predetermined change plans, transparency mandates	Innovation pathways planned with ILAP analog, AI oversight	Still nascent; harmonization focus, but adaptive tools are developing
Transparency & ethics	Public SSCPs via EUDAMED, notified bodies scrutinized	FDA's SaMD docs emphasize transparency, safety validation	ML transparency principles co-authored globally	Ethical frameworks referenced from the WHO, but uneven practice

Aspect	EU	USA	UK	SSA
Regulatory coordination	MDCG coordinates across EU states	FDA coordinates nationally, part of the IMDRF	MHRA leads national strategy; NHS liaison	AMRH and AMA aim to unify regional compliance

5.1. Risk-Based Stratification

The EU legislative framework, in the case of the Medical Device Regulation (MDR 2017/745), uses a system of risk classification that caters to devices that fall under four classes (I, IIa, IIb, III) based on their indicated use and corresponding risks. Riskier devices in this instance face more stringent pre-market evaluation, clinical examination, and post-market vigilance. USA adheres to the IMDRF risk classification, specifically by FDA's SaMD (Software as a Medical Device) guidance, which further categorizes products based on the importance of information delivered and patient effect. The UK, by MHRA guidelines, adopts a similar risk-based strategy by classifying medical devices and digital mental health technologies (DMHT) I–III with specificity as to when digital solutions are therapeutic or diagnostic. On the other hand, SSA's regulatory environment is yet to be defined; although risk-based models have been initiated in some nations (e.g., South Africa), most tend to depend on general or ad-hoc classification systems. Regional programs such as the African Medicines Regulatory Harmonization (AMRH) are developing harmonized risk categorization, but it's implemented differently.

5.2. Adaptive Frameworks

In the EU, the MDR system places a significant emphasis on post-market surveillance, with manufacturers being required to gather and evaluate real-world evidence to continue monitoring device safety and performance on an ongoing basis. This allows for iterative optimization and risk management. The USA moved strongly with its FDA AI/ML Action Plan that brings in the idea of "predetermined change control plans," under which flexibility is possible in regulatory responsiveness in adaptive algorithms and AI-driven healthcare devices without losing transparency and safety. The UK's MHRA strategy is also moving towards adaptive regulation, that is, through initiatives such as the Innovative Licensing and Access Pathway (ILAP) to speed up approval of new products, including digital health. Post-market feedback in SSA has less developed adaptive settings, but mechanisms of reliance and WHO-level collaborative mechanisms are starting to incorporate post-market feedback, principally through initiatives such as the AMRH and the African Medicines Agency (AMA). These are attempts to enable responsiveness and flexibility in regulatory mechanisms, though development is at a very nascent stage.

5.3. Transparency and Ethics

Transparency is also an underlying principle in all the regulations, but is applied with different intensity. Public release of summaries of safety and clinical performance (SSCPs) through the EUDAMED database is mandated in the EU's MDR to facilitate access by clinicians and patients to correct information on medical devices. Labeling transparency, user manual transparency, and risk communication transparency are emphasized in the USA's FDA SaMD guidelines, particularly for software- and AI-enabled products. The UK MHRA has also been contributing to international openness initiatives through co-establishing standards of AI/ML transparency with Health Canada and the FDA, with an emphasis on accountability and prioritization of transparent reporting of AI capability and limitation. Transparency remains an issue in SSA, however, since WHO and AU guidelines firmly place value on ethical monitoring and transparency with end-users, applying openness policies in practice varies widely between countries, and some agencies are still struggling to develop procedures to report on safety and efficacy.

5.4. Regulatory Coordination

Regulatory coordination is one of the strongest predictors of effective regulation of health innovation. Coordination between member states in the EU is provided for by the Medical Device Coordination Group (MDCG) to align regulatory requirements and make decisions palatable to every member. The USA FDA is not only one national regulator but also works through the International Medical Device Regulators Forum (IMDRF) to promote global harmonization of regulatory standards. The national regulator in the UK is the MHRA, and it

works alongside NHS digital health initiatives and has a role in global harmonization, particularly in the post-Brexit environment, so that UK regulation is based on international best practice. SSA coordination is a two-way street. The AMRH programme and the establishment of the AMA are significant regional harmonization and legitimation of action initiatives by regulators. Both programmes aim to streamline the approval process, avoid duplication, and expand access to health innovations, but vary in terms of coordination and integration among regional countries.

6. Discussion

The review revealed an interesting outcome of the convergence and divergence of the EU, USA, UK, and SSA regulatory frameworks for innovation in the health industry. Overall, it can be observed that while the EU, USA, and UK have highly sophisticated risk-based stratification systems, SSA is evolving and harmonizing the same. In the EU, the four-level risk categorization of the MDR provides that medical devices are regulated according to their risk categories (Verma and Baldi, 2025). The MDR framework provides high patient protection and can also promote innovation due to the predictability of clinical evaluation and post-market surveillance obligations. The USA's IMDRF-derived risk-based approach to SaMD, complemented with the FDA's AI/ML Action Plan, is pragmatic in facilitating pioneering AI technology development while having robust control (Mascarenhas et al., 2024). The UK's concurrent stratification under MHRA and other specialists for digital mental health technology offers consistency and transparency, but in shaping its regulatory standing post-Brexit (Turton et al., 2021). SSA's reliance on local harmonization efforts like the AMRH and AMA, however, is an interim situation where risk categorization is other than standard, implying a need to bolster capacity and sensitivity to local conditions.

Akpobome (2024) opined that adaptive regulatory frameworks are necessary, especially in this era of high-speed technology development periods such as digital medicine and AI computer software. The review showed that the EU's focus on post-market monitoring and accumulation of real-world evidence is are echo of the global trends towards evidence-based regulation (Lineaweaver, 2016). The USA is implementing a proactive regulation with integrated pre-configured change management controls for adaptive AI, which is an advanced, forward-looking system with continuous improvement capability without compromising patient safety. In addition, UK engagement with the Innovative Licensing and Access Pathway (ILAP) is an indication of preparedness to implement adaptive supervision (Elsakary et al., 2022). But to what extent this has been accomplished to any great extent is irrelevant (Elsakary, 2022). SSA adaptive tools are in development phases (Ngum et al., 2023). Whereas models like the AMA create precedence for adaptive regulation, enactment on a national level is largely averted by cost as well as heterogeneity of regulatory complexity (Abdulwahab et al., 2024). This emphasizes the necessity of investment in regional regulation and capacity for cooperation to balance the innovation gap.

Transparency and ethics are cross-cutting issues with various degrees of institutionalization across the regions. The public availability of the Summary of Safety and Clinical Performance (SSCPs) by the EU and access through the EUDAMED database reflect high degrees of transparency and reliability ahead of the public. The USA's FDA guidance again brings to mind the requirements of open labeling and risk communication, particularly in the case of software-based medical devices (Scott et al., 2024). The UK's dedication to its international partners in collaborative development of open AI/ML standards is also the articulation of a vision for a better future to align regulative requirements and ethics (Mirakhori and Niazi, 2025). SSA, however, is confronted with a stark reality in providing transparency and ethical regulation with the many infrastructure failures, decentralized regulatory control, and absence of public participation. While WHO guidelines provide general recommendations, there is a policy-practice gap, and regional models that prioritize community involvement and trust in the regulatory framework are known to be essential.

Regulatory harmonization is a key characteristic of monitoring systems' efficiency and effectiveness. The EU Medical Device Coordination Group (MDCG) is a prime example of fruitful cross-border collaboration (Taylor et al., 2024). The MDCG facilitates all the member states to share a common standard, thus allowing innovations to be on sale across the entire continent without unnecessary duplication of effort. The USA has a single FDA regulator with worldwide interconnections via the IMDRF to harmonize on the global level (Khan et al., 2024). The UK MHRA has, post-Brexit, attempted to keep international harmonization on the go and take advantage of

the maximum nationwide connections with NHS digital health initiatives (Flear, 2017). SSA regulatory coordination is at the construction phase. AMRH and AMA are welcome steps towards regional harmonization and acceptance, but they depend on political will, funding, and the availability of national regulatory bodies with adequate capacity. Closing such gaps is critical to ensure that health innovations find their way to the target population in need without undue delay or regulatory uncertainty.

In sum, the research points out the need to weigh innovation against strict control to provide patient safety as well as public confidence. Although developed countries such as the EU, USA, and UK have made considerable advances in developing responsive, open, and harmonized regulatory frameworks, SSA is trying to build its frameworks under regional harmonization schemes. Regulatory bodies and decision-makers in SSA can learn from these successful mechanisms and tailor their strategies to local realities and ensure that innovations in health are not merely effective and safe but also accessible to those who most need them.

7. Conclusion

This comparative analysis has identified the diverse frameworks for the regulation of health innovation in the EU, USA, UK, and SSA, with areas of convergence and divergence. For the high-income economies, high-risk-based stratification regimes, adaptive systems, open processes, and coordinating regulatory systems together constitute an innovation-enabling framework with assured patient security and public confidence. They have shown that robust, well-resourced systems of regulation can counter the threat posed by the quickening rate of technological innovation, particularly of digital health and AI. On the contrary, SSA's regulatory environment is still under development and is marked by irregular regulation, low capacity, and an increasing focus on regional harmonization through frameworks such as AMRH and the AMA. Even as admirable as the evident commitment to excellence in best international practice seems, functional inhibitors like resource availability, decentralized systems, and varying technical levels of capability hamper uniform implementation of risk-based, adaptive, and open regulatory designs.

The outcome of the study emphasizes the need for continuous investment in regional cooperation, SSA context-sensitive approach, and the building of regulatory capacity to bridge the gap in the regulation of innovation. Governments, regional entities, and global agencies need to come together and render health innovations safe and accessible to all. This balance between stimulating innovation and imposing strict regulation should be prioritized as health innovations continue to evolve in the next several years. There is a need for commitment, adaptability, and close monitoring of local circumstances and needs.

In conclusion, the evidence in this review of documents provides regulators and policymakers with a template, a demonstration of best practice for which they can refer back in regulatory development and implementation. SSA nations can build robust regulatory frameworks that can drive innovation, protect patients, and strengthen health system by learning from the frameworks of others and embracing local diversity.

Author Contributions: All authors contributed to this research.

Funding: Not applicable.

Conflict of Interest: The authors declare no conflict of interest.

Informed Consent Statement/Ethics Approval: Not applicable.

Declaration of Generative AI and AI-assisted Technologies: This study has not used any generative AI tools or technologies in the preparation of this manuscript.

References

Aamir, A., Iqbal, A., Jawed, F., Ashfaque, F., Hafsa, H., Anas, Z. ... & Mansoor, T. (2024). Exploring the current and prospective role of artificial intelligence in disease diagnosis. *Annals of Medicine and Surgery*, *86*(2), 943-949.

Abdulwahab, A. A., Okafor, U. G., Adesuyi, D. S., Miranda, A. V., Yusuf, R. O., & Eliseo Lucero-Prisno III, D. (2024). The African Medicines Agency and Medicines Regulation: Progress, challenges, and recommendations. *Health Care Science*, *3*(5), 350-359.

Akpobome, O. (2024). The Impact of Emerging Technologies on Legal Frameworks: A Model for Adaptive Regulation. *International Journal of Research Publication and Reviews*, *5*(10), 5046-5060.

Alex-Omiogbemi, A. A., Sule, A. K., Omowole, B. M., & Owoade, S. J. (2024). Conceptual framework for advancing regulatory compliance and risk management in emerging markets through digital innovation.

Black, J., & Baldwin, R. (2010). Really responsive risk-based regulation. *Law & policy*, *32*(2), 181-213.

Bowen, G. A. (2009). Document analysis as a qualitative research method. *Qualitative research journal*, *9*(2), 27-40.

Carr, K., Kendal, R. L., & Flynn, E. G. (2016). Eureka!: What is innovation, how does it develop, and who does it?. *Child development*, *87*(5), 1505-1519.

Carroll, N., & Richardson, I. (2016). Software-as-a-medical device: demystifying connected health regulations. *Journal of Systems and Information Technology*, *18*(2), 186-215.

Drahos, P. (2017). *Regulatory theory: Foundations and applications*. ANU Press.

Elden, N. M. K., Mandil, A. M. A., Hegazy, A. A., Nagy, N., Mabry, R. M., & Khairy, W. A. (2023). Health innovations in response to the COVID-19 pandemic: perspectives from the Eastern Mediterranean Region. *Journal of Public Health*, *45*(2), 470-480.

Elsakary, Y., Connelly, B., Scrutton, H., Finocchiaro, D., Heathfield, A., & Bending, M. W. (2022). HPR87 A Review and Analysis of Medicines Following the Innovative Licensing and Access Pathway (ILAP) in the UK: Does the Pathway Lead to Faster Regulatory Approval and HTA Recommendation?. *Value in Health*, *25*(12), S248.

Flear, M. L. (2017). Ensuring post-Brexit UK is a 'maker'rather than a 'taker'of global norms and standards: the case of the International Council on Harmonisation. *Available at SSRN 2992551*.

Gupta, S., Muskens, I. S., Fandino, L. B., Hulsbergen, A. F., & Broekman, M. L. (2018). Oversight in surgical innovation: a response to ethical challenges. *World Journal of Surgery*, *42*, 2773-2780.

Hantke-Domas, M. (2003). The public interest theory of regulation: non-existence or misinterpretation?. *European journal of law and economics*, *15*, 165-194.

Heydon, J., Chakraborty, R., Patel, V., Wood, C., Wood, M., & Bunce, C. (2024). Reconceiving Domestic Burning Controls: Air Quality Alerts, Behavioural Responsive Regulation, and Designing for Compliance. *Environmental Management*, 1-17.

Islam, Q. M. (2021). Innovation in primary healthcare in the twenty-first century. *Journal of Health Management*, *23*(1), 129-142.

Khan, M. I., & Sharma, T. (2024). From Aspiration to Affiliation in IMDRF By 6 Countries (Egypt, Cuba, Chile, Montenegro, Israel And Chinese Taipei) And Investigating the Absence of India. The Academic International Journal of Multidisplinary Research, 2(3), 275 – 303.

Kim, E., Rubinstein, S. M., Nead, K. T., Wojcieszynski, A. P., Gabriel, P. E., & Warner, J. L. (2019, October). The evolving use of electronic health records (EHR) for research. In *Seminars in Radiation Oncology* (Vol. 29, No. 4, pp. 354-361). WB Saunders.

Kirklin, J. K. (2021). Commentary: The swing of the pendulum between innovation and regulation. *JTCVS open*, *8*, 33-34.

Krouse, J. H. (2015). Balancing evidence, innovation, and regulation. *Otolaryngology--Head and Neck Surgery*, *152*(4), 579-580.

Lineaweaver, W. (2016). Evidence-based regulations. *Annals of Plastic Surgery*, *77*(2), 139.

Lipworth, W., Wiersma, M., Ghinea, N., Hendl, T., Kerridge, I., Lysaght, T., ... & Waldby, C. (2021). The oversight of clinical innovation in a medical marketplace. In *The Cambridge handbook of health research regulation* (pp. 287-295). Cambridge University Press (CUP).

Lu, Y., Tsang, E. W., & Peng, M. W. (2008). Knowledge management and innovation strategy in the Asia Pacific: Toward an institution-based view. *Asia Pacific Journal of Management*, *25*, 361-374.

Mascarenhas, M., Martins, M., Ribeiro, T., Afonso, J., Cardoso, P., Mendes, F., ... & Macedo, G. (2024). Software as a Medical Device (SaMD) in Digestive Healthcare: Regulatory Challenges and Ethical Implications. *Diagnostics*, *14*(18), 2100.

Meglio, O., & Di Paola, N. (2021). Innovation and entrepreneurship for well-being and sustainability. *Sustainability*, *13*(16), 9154.

Mirakhori, F., & Niazi, S. K. (2025). Harnessing the AI/ML in Drug and Biological Products Discovery and Development: The Regulatory Perspective. *Pharmaceuticals*, *18*(1), 47.

Morgan, H. (2022). Conducting a qualitative document analysis. *The qualitative report*, *27*(1), 64-77.

Ngum, N., Ndomondo-Sigonda, M., Walker, S., & Salek, S. (2023). Regional regulatory harmonisation initiatives: their potential contribution to the newly established African medicines agency. *Regulatory Toxicology and Pharmacology*, *145*, 105497.

Nurkhamid, M. (2023). Perspektif public choice theory pada pakaian bekas impor di Indonesia dan dampaknya terhadap keuangan negara. *Innovative: Journal Of Social Science Research*, *3*(6), 3173-3186.

Omachonu, V. K., & Einspruch, N. G. (2010). Innovation in healthcare delivery systems: a conceptual framework. *The Innovation Journal: The Public Sector Innovation Journal*, *15*(1), 1-20.

Orina, W. A., Mwangi, G. F., Sitati, R. N., & Nyabola, F. (2015). Content analysis and a critical review of the exploratory design. *Name: General Education Journal*, *4*(2), 32-45.

Paracha, A. (2023). Analyzing the Difficulties and Possibilities of Combining Responsible and Ethical Technological Advancement with Innovation. *Indus Journal of Law and Social Sciences*, *2*(2), 15-22.

Pham, T. (2025). Ethical and legal considerations in healthcare AI: innovation and policy for safe and fair use. *Royal Society Open Science*, *12*(5), 241873.

Ranchordás, S. (2014). Innovation-Friendly regulation: the sunset of regulation, the sunrise of innovation. *Jurimetrics*, *55*, 201.

Rodriguez-Manzano, J., Subramaniam, S., Uchea, C., Szostak-Lipowicz, K. M., Freeman, J., Rauch, M., ... & Awandare, G. A. (2024). Innovative diagnostic technologies: navigating regulatory frameworks through advances, challenges, and future prospects. *The Lancet Digital Health*.

Scott, P. D., Bajaj, A., & McMullen, D. P. (2024). Navigating the FDA regulatory landscape. *Neuropsychopharmacology*, *49*(1), 18-22.

Seymour, T., Frantsvog, D., & Graeber, T. (2012). Electronic health records (EHR). *American Journal of Health Sciences*, *3*(3), 201.

Shaw, J. S. (2002). Public choice theory. *The concise encyclopedia of economics*, 1-7.

Taylor, S., Gilje Jaatun, M., Bernsmed, K., Androutsos, C., Frey, D., Favrin, S., ... & Katzis, K. (2024, June). A way forward for the MDCG 2019-16 medical device security guidance. In *Proceedings of the 17th International Conference on PErvasive Technologies Related to Assistive Environments* (pp. 593-599).

Turton, P., El-Sharkawi, D., Lyburn, I., Sharma, B., Mahalingam, P., Turner, S. D., ... & Mercer, N. (2021). UK guidelines on the diagnosis and treatment of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) on behalf of the medicines and healthcare products regulatory agency (MHRA) plastic, reconstructive and aesthetic surgery expert advisory group (PRASEAG). *European Journal of Surgical Oncology*, *47*(2), 199-210.

Ugochukwu U., C. (2001). The theory of regulation: A review article. *Journal of Financial Regulation and compliance*, *9*(1), 67-80.

Vasiljeva, K., van Duren, B. H., & Pandit, H. (2020). Changing device regulations in the European Union: impact on research, innovation and clinical practice. *Indian journal of orthopaedics*, *54*, 123-129.

Verma, S. J., & Baldi, A. (2025). Evidence-based recommendations for comprehensive regulatory guidelines in medical devices: the imperative for global harmonization. *Naunyn-Schmiedeberg's Archives of Pharmacology*, 1-15.

Wiersma, M., Kerridge, I., & Lipworth, W. (2023). Clinical innovation ethics frameworks: a systematic narrative review. *Health Policy*, *129*, 104706.