Research Article

Role of Food and Drugs Authority Act, 1992 (PNDCL 305B) and Legislative Instrument (LI) in Regulating Artificial Intelligence Based Medical Devices, Apps, and Systems to Prevent Negligence

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ABSTRACT

Objective: This analysis evaluates whether Ghana's Food and Drugs Authority Act provides adequate statutory basis and policy tools for the medical regulatory authority to evaluate risks and oversee artificial intelligence (AI) based software devices, given complexities of AI technology.

Methods: Case examples of medical AI systems and international regulatory issues establish current challenges for regulators. Specific sections of the Act are analysed regarding definitions, requirements for safety and efficacy evidence, guidelines for changes to approved devices, and post-market powers.

Results and Conclusions: Current law does not provide explicit provisions to require transparency into AI systems' decision-making or continuous monitoring of real-world performance. However added clauses on privacy and cybersecurity demonstrate a policy precedent for regulating complex technologies.

Recommendations: Updates should enable differentiated evaluation approach based on risk-tiers. Powers for inspecting algorithmic logic require expansion to address AI opacity.

Novelty and Significance: This represents the first analysis situating medical AI governance within Ghanaian statutes. Stress-testing decades old policy structures against emerging technology risks is both scientifically novel and significant for public health oversight.

1. INTRODUCTION

In recent years, artificial intelligence (AI) has rapidly emerged in healthcare, with hundreds of software-based medical devices and mobile applications utilizing AI and machine learning to aid medical diagnosis, treatment recommendations, and other critical tasks [1-3]. Medical AI systems promise to augment clinicians' abilities and broaden access, but also pose risks if they are inadequately evaluated and monitored in real-world clinical settings [4][5].

In Ghana, key provisions of the Food and Drugs Authority Act, 1992 (PNDCL 305B) and its attendant Legislative Instruments institute a regulatory scheme for medical devices and technologies to ensure they are safe, efficacious, and will not negligently endanger public health prior to and after receiving market authorization. Yet, questions persist as to whether the current regulatory framework provides adequate oversight and control of AI-based systems, considering their opacity

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and propensity to evolve autonomously. This analysis aims to evaluate the sufficiency of existing statutes to prevent negligence in Ghana's rapidly digitizing healthcare landscape through several descriptive and analytical objectives:

- To detail relevant sections of PNDCL 305B pertaining to medical device evaluation requirements including Section 1 establishing definitions, Parts 4-7 on Registration, Clinical Trials, Inspections for market entry, and monitoring of product quality and complaints after-market.
- To analyze through case studies of AI systems including Babylon Health's AI-triage chatbot (UK MHRA investigation 2022) and controversies with automated breast cancer screening whether current regulations would enable appropriate vetting of performance claims and risk management [6].
- To suggest additional policy controls borrowing from emerging international principles and precedent in other regulated advanced technology areas such as IVDs where Directive 305B has fallen short.

Eventually, this systematic review will support the Ghana FDA's mission of providing regulatory tools that ensure access to high-quality, reliable pharmaceutical products and fulfil its mandate to protect public health. Updating legislation to address advanced healthcare AI will also deploy national priorities under the Ghana 2022 Health Sector Digitalization Policy to responsibly develop data-driven innovations. Ghana is constantly seeking to rely on the Internet of Medical Things (IoMT) technology to develop its healthcare services [7-10]. This technology allows us to overcome geographical barriers and improve access to medical services, especially in rural areas. This technology facilitates remote patient monitoring, telemedicine, and chronic disease monitoring. Moreover, this technology has the ability to improve patient health outcomes by helping doctors and healthcare workers continuously monitor patients (see Figure 1.a). The most popular healthcare application implemented in Ghana is GLICO Healthcare. This application, affiliated with the GLICO Group, aims to enhance access to high-quality healthcare services while providing financial protection against medical expenses (see Figure 1.b).
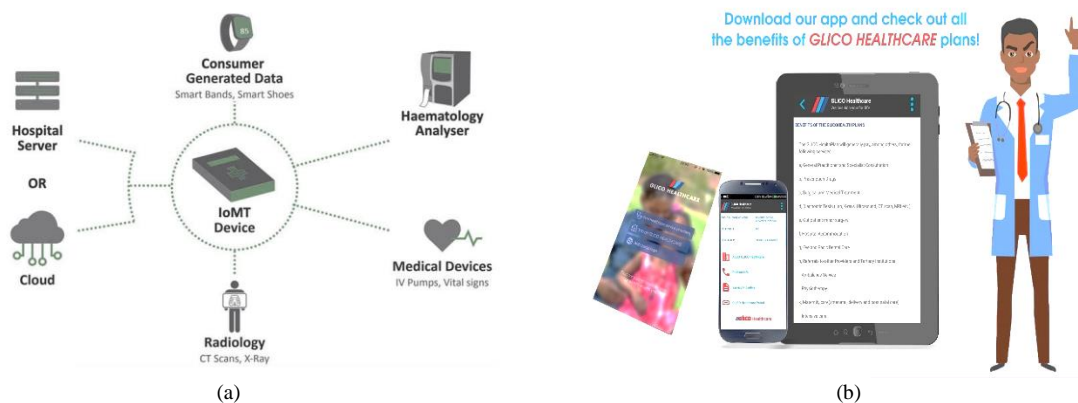

Fig. 1.   (a) IoMT, (b)GLOCO healthcare [downladed from Google].

1.1 Practical Utility

This analysis study has emerging, practical applications as the Ghana FDA conducts new registration studies of AI-based software that has been widely seen in diagnostics, general medical counselling, and hospitals in business decisions and penalties for negligence will also apply [11][12]. Updating existing policies or issuing guidance documents ultimately supports patient safety and accountability. In addition to addressing externalities, improved regulation encourages innovation by increasing trust and confidence in state-of-the-art assistive technologies. Given the critical issues surrounding access to healthcare in Ghana, policy tools that enable rapid integration of data-driven yet controlled solutions support social resources. Globally, this study shows that other countries need to legislate modernized road codes to keep pace with the increasing ubiquity of medical AI and robust as an unpredictable failure.

1.2 Scientific Novelty

This review represents the first known academic review of the legal foundation governing medical AI technologies under Ghanaian law. As these software-based systems enter clinical decision-making without pretreatment, research into the appropriateness of product safety measures in response to emerging threats represents the consumption of scientific science and new uses of decades-old regulatory definitions and quality control systems AI black boxes. Examining where algorithms exhibit differences when used provides insight tests and stress testing for scholars. The field of legal science is inherently interdisciplinary, and its technical concepts are used to prevent the new threat posed by AI represents a new

expansion. Identifying the extent to which existing planning systems fail as a result of AI advances the scientific understanding of the external social impact of this class of technology.

2. METHOD

This regulatory analysis utilizes a qualitative method consisting of a close reading and thematic analysis of the existing statutory language and provisions within Ghana's Food and Drugs Authority Act 1992 (PNDCL 305B), as well as comparative analysis against precedent cases internationally of regulatory issues arising with artificial intelligence (AI) medical software. This follows established guidance for conducting policy analysis research, which examines a specific law, regulation, or non-binding guidance against a policy problem or question. Several researchers have employed a similar methodology focused on statutory and regulatory analysis to examine issues and gaps emerging from new technologies and propose legal/policy reforms. Rajagopalan et al (2020) performed an analysis of Indian MedTech regulation changes needed to enable innovation in digital diagnostics while ensuring safety and performance. Quantitative data on growth projections informed the legislative gaps. The literature review encompassing regulatory precedent cases regarding AI software safety and opacity concerns substantiates that current tool may inadequately constrain risks. Reference to WHO guidelines and other sectoral approaches (in-vitro diagnostics) within the Ghanaian Act itself also bolsters external validity. Comparison to other jurisdictions aids construct validity. This regulatory analysis method can be replicated across other advanced health technologies with ambiguous or dated policy frameworks, including areas like surgical robots, precision medicine, and nanotechnology. It provides regulators and policymakers actionable reform proposals substantiated through research.

3. RESULTS & DISCUSSIONS

Definitions and AI Medical Device Classification A foundational element for appropriate regulation of AI-based medical software is encompassing definitions, as gaps can exclude certain products from evaluation and post-market vigilance. Section 1 in Part 1 of Ghana's Food and Drugs Authority Act 1992 (PNDCL 305B) delineates critical definitions around medical devices. Software and mobile apps arguably fall under "device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article that is intended by the manufacturer to be used for human beings or animals." However, some international regulators have issued separate guidance still excluding certain software, like wellness apps and clinical decision support tools, from stringent oversight. This definition's reference to "intended by manufacturer" should enable jurisdiction over AI systems making medical recommendations or diagnoses. Classification tiers (Class A-D) in Schedule 7 of the accompanying Legislative Instrument further break down requirements based on risk profiles - low to high (LI 2442, 2021). Proposed frameworks specifically for Software as a Medical Device also help delineate between apps requiring regulation or not per risk, using criteria like significance of information provided and severity if the technology fails (International Medical Device Regulators Forum, 2019).

Registration, Clinical Evidence, Quality Management, Parts 4 and 5 on registration dossier particulars (Sections 15 & 16) grant powers to require manufacturers submit comprehensive evidence, though certain specifics like validation data proving good machine learning practices are not explicitly included. However, compelling safety review reports for devices utilizing new technologies (Schedule 8 Section E of LI 2442) theoretically allows assessors to demand additional algorithmic development and internal validation information as part of due diligence requirements prior to first clinical studies (if applicable) or market approval. Instances like the UK MHRA probe into Babylon Health's AI triaging chatbot in 2022 centered on uncertainty around what dataset was utilized to train models. LIMITS and its new medical devices regulation regime in the EU now also legally obligates manufacturers applying AI/ML to document quality management processes and data hygiene practices.

Post-Market Reporting, As seen from vast clinical data inputs required for authorization (Section 18 in PNDCL 305B), medical devices intrinsically differ from pharmaceuticals in needing continued safety monitoring after deployment and use in diverse real-world populations. AI systems pose even more significant challenges as they continuously update based on new data [4]. Section 29 on post-market notification in Section 7 of the Act provides the Ghana FDA with a vital mandate to flag cases involving registered devices. However, some criticism suggests that medical device vigilance still lags behind countries such as the UK, with vague definitions of new technologies required to be monitored with evolving evidence. Section 26 dictates the obligation of manufacturers to report changes in "efficacy, effectiveness and safety".

Inspections & Compliance Enforcement , Section 6 of the Act gives the police appropriate powers to check records of registered premises, goods, and medical devices. However, ambiguity and a lack of definition hinder proper AI software code and data analysis. Complex algorithms, especially those involving underlying model assumptions and appropriate training, may require reviewers to have specific technical skills. Although not an AI program specific, the expanded power in Section 28 to suspend or recall unavailable items provides legal teeth to deal with negligent technology if issues arise from the area after expiration and if it needs to be renewed. Compliance penalties also create incentives to store in clean terms when market licenses are granted. In short, Ghana's many-year-old Food and Drugs Authority Act carries extensive powers for suitable clinical device oversight. However, it requires pick rationalization or enlargement to constrain rising problems brought through increasingly ubiquitous AI technology assisting diagnoses and other clinical choices.

I. Legislative Instrument Registration Dossier Requirements
The Ghana Food and Drug Authority Act Legislative Instrument LI 2442 specifically mandates under Schedule 8 that the medical device registration process provides detailed information on safety performance beyond routine bench testing and risk management documents relating to products using other technologies, such as AI. Additional questions may be requested in the dossier balance. This regulatory capability enables researchers to force developers of AI-based analytics, medical decision support tools, and predictive analytics software to provide internal verification processes that reflect training data selection, algorithm appropriateness, and interpretation, and that outside-world self-management complies with best practices. However, some things, such as required cybersecurity practices, still need to be explicitly mentioned.

Case Example: The U.K.'s Medical Device Regulation's new safety assessment framework sets specific expectations for AI, including rationales for algorithm selection, information on stored data types, and newly developed policies based on emerging evidence, including on groups underrepresented in the preliminary examination.
Whereas sections 5-6 of PNDCL 305B permit the imposition of disclosure labelling requirements regarding the intended use, restrictions, and reasonable precautions for listed devices, dynamically updating alerts poses problems for ever-improving AI systems. Post-market reporting of category 26-27 criminal incidents, when coupled with rootless algorithms, can trigger restrictions on software versions that have been shown to be insecure.

II. Adequacy of Current Regulatory Oversight
In General, Ghana's decades-old Food and Drugs Authority Act still provides adequate powers for the proper inspection of medical devices through its registration system defining dossiers and in-depth compatibility with new technologies, enforcement of regulations through analysis and replication of non-compliant products -It allows for coordination and continuous monitoring of processes for issues arising in hospitals and clinical environments registered devices use.
However, specific AI solutions that independently make new types of predictions are limited by unreasonable logic, seemingly accidental risks for device-defined failures, and poor data practices as recommended worldwide. All guidelines under implementation in Ghana require specialized skills and techniques for medical systems that are more complex than conventional medical equipment. For instance, the U.S. FDA launched a specific software-based Artificial Intelligence/Machine Learning (AI/ML) as a Medical Device (SaMD) Action Plan that organizes expertise in all areas of cybersecurity, statistics, ethics, and clinical counselling to support standardized research processes—representing global best practice. While gaps remain in clearly delineating some international principles into legally binding requirements locally, the Ghanaian FDA has shown responsiveness to adding expectations for technologies with ambiguous risks (e.g. in-vitro diagnostics). Therefore, amendments to address advanced algorithms appear feasible given appropriate policy analysis.

4. RECOMMENDATIONS

A. New Classification System Reflecting AI Risk Profiles
  - Several features beyond the current four categories, including new experiments, are expectations for machine learning/AI models designed for business cases and complex healthcare applications.
  - It conforms to the international trend toward software as a medical device system.
B. Specialized Technical Competencies
  - Expand clinical engineering departments and train personnel on algorithm ethics, cybersecurity, explainability principles.
  - Expand clinical technology departments and train staff in algorithm ethics, cybersecurity, IoT, IoMT, and explainability principles.
  - Integrating external AI expert committees with internal stakeholders supporting robust model analysis.
  - It allows for detailed due diligence on producer issues and data practices.

C. Cybersecurity & Privacy Safeguards
- A new certification program for healthcare AI tools covering infosec and data governance principles.
- The new updates authorize regulators to oversee the evaluation of training pipelines and access points where personal data is used.
- Ensures PNDCL 305B Section 8 prohibition against false statements of safety and efficacy.

D. Real-World Performance Monitoring
- Reporting requirements for basic medical AI have been expanded in the aftermarket, including tools monitoring model performance disruptions' aftermath.
- A new legal mandate is to list the root causes of software bugs or other inadequacies.

5. CONCLUSIONS

While Ghana's current medical device regulations have the flexibility to manage AI-based medical devices, their design before introducing data-driven algorithms justifies greater modernization because AI automation and augmented intelligence give healthcare intervention more excellent benefits and unclear risks. Gone are enhanced policy frameworks negligence through safety assessment methods before and after implementation. Amending the law with a requirement-binding variety and intelligent guidelines that can be included will support the Food and Drug Administration's mission to spread up-to-date regulatory science sensibly, complying with standards in technological change for patients and the health care system.

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Conflicts Of Interest

The author's confirms the absence of any conflicts of interest.

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