Impact of Digitalization in strengthening the regulatory functions of NAFDAC: Opportunities and Challenges for other National Regulatory Authorities

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ABSTRACT

The digitalization efforts employed by the National Agency for Food and Drug Administration and Control (NAFDAC) as a National Regulatory Authority (NRA) to strengthen its regulatory functions represents a paradigmatic shift from an outdated method to digital innovation and automation of its regulatory processes. This review analyzes the impact of digitalization and automation of regulatory functions in NAFDAC and the significant contribution of digital innovation to the landmark achievements of the Agency as a WHO-ML3 NRA, including becoming a Prequalified Laboratory by the World Health Organization. This synopsis also examines the technological components of digitalization deployed by NAFDAC and the inherent opportunities. Gains from digital innovation include promoting regulatory efficiency, data integrity, improving efficient management of human resources, minimizing the prevalence of Substandard and Falsified Regulated Products, improving real-time access to regulatory information, enhancing transparency, and improving public confidence. Digitilization also strengthens regulatory collaborations between the Agency and other NRAs around the globe. The discourse further evaluates the role of digitalization in the assessment of regulatory functions of NRAs for Global Benchmarking Tools and Maturity levels by the World Health Organization and summarizes challenges in the digitalization of regulatory functions. Thus, embracing digital innovations and modern technologies in regulatory processes is a transformative and innovative strategy to promote regulatory efficiency, data integrity, and effectiveness in strengthening the regulatory functions of NRAs.

Keywords: NAFDAC; WHO; digitalization; innovation; regulatory

Introduction

National Agency for Food and Drug Administration and Control (NAFDAC) is a National Regulatory Authority (NRA) established by Decree No. 15 of 1993 as amended by Decree No. 19 of 1999 and now the National Agency for Food and Drug Administration and Control Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004. The Agency is mandated by the law to regulate and control the manufacture, importation, exportation, distribution, advertisement, sales, and use of Food,

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Drugs, Cosmetics, Medical Devices, Packaged Water, Chemicals, and Detergents (collectively known as regulated products) (NAFDAC 2024)

Over the last six years, the Agency has improved the Nigerian healthcare landscape by implementing stringent regulatory measures to strengthen its regulatory functions, eliminate substandard regulated products, fake and falsified medicines, improve access to quality medicines and promote public confidence in both locally manufactured and imported regulated products in the country through digitalization. The introduction of digital innovation and automation for its regulatory processes in recent times was a turning point for the Agency to be more efficient and more effective in performing its regulatory tasks and workloads. Most importantly, digitalization of some of the regulatory functions has played a pivotal role in the Agency achieving global recognition as a WHO Global Benchmarked Maturity Level 3 (WHO-GBT ML3) National Regulatory Authority in Sub-Sahara Africa (NAFDAC 2022, WHO N.D)

Through digitalization, the Agency has been able to streamline some of its regulatory functions such as online submission of applications for regulatory services, electronic processing and approval of Marketing Authorization, submission and review of CTD dossiers for drug registration for human use, Clinical trials review, Laboratory testing, Port Clearance, Vigilance, Post-Market Surveillance, and Control. Particularly, digitalization is a key component of the agency' Quality management system (QMS) that aids ISO certification for some of the regulatory processes of the Agency. These digitilization strategies have assisted the agency in prequalifying as a WHO prequalifies laboratory.

This review examines the driving impact of digitalization on the regulatory functions in NAFDAC, including, challenges and opportunities.

NAFDAC's journey towards automation of its regulatory processes.

The journey embarked on by the Agency towards digitalization and automation of its regulatory functions marks a significant transformation from conventional methods of regulatory processes to an unprecedented technological approach in the regulatory space. This digital transformation has displayed immense opportunities and paved the way for effectiveness, transparency, and efficiency in regulatory strengthening as an NRA.

Until recently, NAFDAC relied majorly on manual processes, and paperwork with obsolete tools and limited resources. These conventional approaches were time-consuming, inefficient, not transparent, and unreliable to handle the increasing complexities of regulatory tasks. Consequently, the Agency resolved to adopt technological intervention through digitalization and automation of its regulatory operations.

The agency began by transitioning manual tasks into automated workflows with the goal of to streamlining most of NAFDAC regulatory processes such as submission of applications for product registration, approvals for marketing authorization, issuance of compliance directives, submission of inspection reports, and track-and-trace solutions to enhance post-marketing surveillance and monitoring capabilities, and so on.

Similarly, the deployment of user-friendly online portals and integration of digital technologies by the Agency facilitates good access to regulatory information, relevant guidelines, and submission procedures

through online portals. This has significantly enhanced proactive regulatory interventions, transparency, real-time data analytics, and improved confidence between the Agency and the public.

Furthermore, NAFDAC's journey from manual to automation of regulatory processes reflects a transformative strategy, leveraging digital innovation to modernize operations, boost efficiency, improve resource management, and adapt to the dynamic challenges of regulations as an NRA.

Objectives of digitalization of regulatory functions in NAFDAC

The objectives of digitalization of regulatory functions by the Agency are as follows:

- Automation of regulatory processes, including electronic submission of applications for product registration, digital processing of marketing authorization and approvals, issuance of compliance directives electronically, to reduce processing times, mitigate human errors and enhance accuracy.

- Improving surveillance and monitoring capabilities with the use of data analytics and track-and-trace solutions that enable real-time monitoring of products and facilities to identify non-compliance issues promptly.
- Improving data accessibility, accuracy and integrity by establishing a robust information management system for regulatory data, including digital databases with secure storage and efficient retrieval systems.

- Streamlining communication among stakeholders through digital platforms and portals by creating user-friendly online interfaces for information dissemination, inquiries, and submissions.

- Implementation of track-and-trace solutions (Traceability) using technologies such as RFID, barcoding, or blockchain to ensuew transparency and confidence in the supply and distribution of regulated products from the manufacturers/ distributors to the final consumers.

- Leveraging of data analytics tools enables to process large volumes of data efficiently to derive meaningful insights from regulatory data, enabling informed decision-making, trend analysis, and risk assessment in regulatory activities.

- Utilizing cloud-based solutions offers scalability, flexibility, and cost-effectiveness in managing regulatory data and applications providing access from remote locations

- Implementing robust cybersecurity measures to safeguard sensitive regulatory data and systems by using encryption, access controls, regular security audits, and compliance with data protection regulations.

- Developing mobile applications or providing remote access to regulatory information and tools improves accessibility and enables stakeholders to interact with regulatory systems

- Building user-friendly digital platforms and portal to improve communication, information sharing, and collaboration among stakeholders. The digital platforms include online submission portals, regulatory databases, and public information systems.

- Implementing a continual improvement process to technological adoption to ensure that NAFDAC operations remain at the forefront of regulatory innovation among NRAs in the world.

Digital Tools within NAFDAC

Digital technologies have reshaped how NAFDAC interacts with clients and relevant stakeholders in recent times throught the development of online platfroms.portals. These channels facilitate communication via online portals and promote customer support by enhancing the overall customer experience and not downplaying the importance of flexibility provided by digital tools for remote work experience.

a. **NAFDAC Automated Product Administration and Monitoring System (NAPAMS):** This e-registration portal provides online submission of applications for product registration, and approval for marketing authorization electronically for regulated products. This platform streamlines marketing authorization, promotes transparency, and enhances efficiency and accountability among all stakeholders.

b. **DMS Dossier Management System (DMS):** This is a robust web-based portal that provides online submission, screening, and assessment of pharmaceutical common technical documents known as CTD Dossier as a critical requirement for registration of human medicines in line with International Council on Harmonization (ICH). The portal promotes regulatory collaborative procedure, efficiency, transparency, accountability, and effective communication between the Agency and applicants and it ensures data integrity across the life cycle of the application process.

c. **Laboratory Information Management System (LIMS)**: LIMS is an on premise software designed to efficiently manage laboratory samples for analysis and associated data on laboratory reports. It enables workflow automation, integration with instruments, and centralised access to quality control data of laboratory results. It provides easy tracking and managing of laboratory samples for analysis, efficiency and accuracy in producing and keeping reliable results. Key tasks supported by LIMS include workflow automation, centralized quality control data storage of laboratory results, compliance support, reagents and lot tracking, instrument run monitoring, initiation of downstream data analysis, and integration with in-lab systems.

d. **Ports Inspection Data Capture and Risk Management System (PIDCARMS):** This is an online portal for processing the port clearance and release of regulated products imported through Nigeria's airports, seaports and land borders. The system captures and archives data obtained from Port Inspection Directorate (PID) for routine clearing processes. Data relating to NAFDAC Regulated Products obtained from the Nigeria Integrated Customs Information System (NICIS) are also stored and further processed on the PIDCARMS. Some of the tasks that can be managed by PIDCARMS include Assessment/Invoicing, Payment Receipts Management, First Endorsement, Violations Handling, Fast Track Scheduling, HOLD Management, Field and Fast Track Inspection Reporting, Clearance and Release

Notification, Post-Clearance Audits and Statistical Reporting.

e. **NAFDAC Traceability Information System (NTIS):** This is an online platform designed to enhance visibility within the supply chain. It facilitates the monitoring of potentially suspicious activities by analysing traceability data obtained through the automatic scanning of 2D DataMatrix barcodes. These barcodes encode essential product information such as the Global Trade Item Number (GTIN), Batch or Lot, Expiry Date, and a unique serial number. The NTIS includes a dashboard that presents data from the centralized traceability repository, along with integrations to external systems connecting manufacturers and pre-country traceability systems for seamless data exchange and product verification.

f. **Electronic Clinical Trial Application (eCTAP)**: This web base portal facilitates online submission of Clinical trial applications. The portal provides opportunity for transparency, accountability, efficiency in the clinical trial process.

g. **Med Safety App:** This is a mobile application developed to engage both patients and healthcare providers on medicines safety issues or complaints. The app is designed to simplify and promote the reporting of suspected adverse drug reactions (ADRs), including adverse events following immunization (AEFIs) by both the public and healthcare providers.

h. NAFDAC Greenbook: This is an online repository platform for human medicines registered by NAFDAC. The platform is available to the public. Individuals can search for information on the status of registered medicine for human use, the manufacturer's details, Active ingredients, applicant details, and product classifications.

Impact of Digitalization

The implementation of Digital Innovation and Technological Tools has significantly repositioned the Agency among other NRAs in the world. Achievements include attaining status as a WHO Benchmarked ML3 and WHO Prequalified Laboratory (NAFDAC 2024b). These digital tools have improved efficiency within the agency by minimizing human errors and undue delays.

a. **Promote Regulatory Efficiency:** Digitalization has automated and streamlined some of the regulatory functions of the Agency, including the automation of registration systems and the implementation of electronic submission systems, by reducing bottlenecks and minimizing paperwork. Digital tools facilitate the planning, execution, and documentation of inspections by enabling assessors to review the reports for compliance during assessments.

b. **Resource Management:** Digitalization has helped to automate repetitive tasks by allowing limited staff to perform more regulatory tasks within a short time. In addition, NRAs can use data analytics and performance metrics to analyse regulatory data, track key performance indicators, and identify areas for improvement to meet WHO's standards.

c. **Tackling Counterfeit and Substandard Products:** Digital technologies have been very instrumental in enhancing post-

marketing surveillance, monitoring, and detection of substandard and falsified regulated products to combat the menace of counterfeiting in the country.

d. **Improving Access to Regulatory Information:** Digital innovation has improved access to relevant regulatory information through online platforms and digital systems that can be used to maintain databases, track regulatory activities, and share information with WHO and other NRAs seamlessly in real-time.

e. Promote and institutionalize transparency and accountability: Digital platforms foster unity, public confidence transparency and promote trust between the Agency and its clients by ensuring that regulatory processes are transparently documented, enabling WHO assessors to review and validate procedures.

f. Facilitate collaboration and capacity building: Digital platforms can contribute to capacity building among NRAs and WHO by facilitating the sharing of Online training modules, webinars, and knowledge-sharing platforms

Challenges in the digitalization of regulatory processes

Digitalization of regulatory processes, while offering numerous opportunities, also presents certain challenges to regulatory authorities, including:

a. **Resource Constraints:** Limited funding and resources might hinder the implementation of robust digital systems and technologies within regulatory authorities. This could include budget limitations for acquiring and maintaining digital infrastructure, software, and skilled personnel.

b. **Data Security and Privacy Concerns:** Protecting sensitive regulatory data and information from cyber threats, unauthorized access, and breaches requires robust cybersecurity measures pose a great concern.

c. **Technological Infrastructure and Connectivity:** In some regions, inadequate technological infrastructure and poor internet connectivity might impede the seamless implementation and utilization of digital systems and result in disparities in access and usage among different geographical areas.

d. **Capacity Building and Knowledge Gaps:** Adopting and effectively utilizing digital tools may require specialized skills and training that may not be easily available in certain regions.

e. **Interoperability and Standardization:** Ensuring interoperability between different digital systems and standardization of data formats can be challenging. Lack of compatibility between systems may hinder seamless data exchange and collaboration among NRAs.

Conclusion

The impact of digitalization on strengthening the regulatory functions of NAFDAC as an NRA has been very significant over the years. Digital innovation has played a critical role as one of the contributing factors to the landmark achievements of the Agency in recent times, including achieving the designations of Global Benchmarked, WHO-ML3, and WHO-Prequalified Laboratory NRA. At NAFDAC, digital innovations and technologies have proved to promote

regulatory efficiency and data integrity, improve real-time access to regulatory information, enhance transparency, and build public confidence. Therefore, continuous investment in digitalization, digital innovations, and automation of regulatory processes would not only advance the repositioning of an NRA but also strengthens the capability and adaptability of NRA to emerging global regulatory challenges and workloads.

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