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RESEARCH ARTICLE

Covid-19 Pandemic and Medicines Regulation in Ghana: Overview and Perspectives of Regulators

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ABSTRACT

Background: The novel coronavirus SARS-CoV-2 pandemic, impacted health systems around the world resulting in a surge in demand for medicines and therapeutic interventions to combat the pandemic. Medicine regulatory agencies played a crucial role in ensuring the safety, quality, and efficacy of medicines. Regulatory agencies streamlined regulatory processes and made them flexible to tackle the urgent need for COVID-19 interventions. The COVID-19 pandemic prompted regulatory agencies on the importance of global regulatory collaboration and harmonization. Following the pandemic, regulatory agencies continually aim to ensure global alignment in regulatory standards, facilitate data sharing, and streamline regulatory processes to optimize their activities and preparedness for future emergencies.

Objective: The objective of this study was to have an overview of medicines regulation following the emergence of the COVID-19 pandemic and regulator's perspective on the associated regulatory adaptations.

Method: The study was conducted through qualitative open-ended interviews. It was carried out within the head office of the Ghana Food and Drugs Authority; the sole regulator of medicines in the country. Interviews were audio-recorded with the consent of participants and transcribed for analysis. After transcription data was categorized into themes and analyzed using a generic thematic analysis method.

Results: Ghana's medicines regulatory system, governed by the Food and Drugs Authority (FDA) developed a system which encompassed pre-market approval, post-market surveillance, pharmacovigilance activities, and approval of clinical trials, aimed at safeguarding public health. To address the urgent need for COVID-19 treatments and vaccines, regulators worldwide, including Ghana, implemented emergency use authorization (EUA) processes, demonstrated regulatory flexibility by adopting alternative assessment approaches and streamlining processes without compromising safety and quality standards. The Food and Drugs Authority along with other stakeholders and opinion leaders played a crucial role in disseminating accurate information and debunking myths and misconceptions about the pandemic to empower citizens with accurate information, dispel misinformation, and promote adherence to preventive measures.

Conclusion: The importance of resourcefulness and the adoption of sustainable practices, working smarter, saving resources, embracing virtual trainings, and introducing dynamic assessment practices have been highlighted to have reshaped activities of the Authority. These lessons can serve as valuable guides in building a more efficient, collaborative, and environmentally conscious future as we continue to navigate the post pandemic world.

Introduction

The COVID-19 pandemic, caused by the novel coronavirus SARS-CoV-2greatly impacted health systems around the world. The result of this was a surge in demand for medicines and therapeutic interventions to combat the pandemic. The associated impact on medicine regulation became crucial to ensure continuous availability of safe, effective treatment, and management options during the public health crisis. The COVID-19 pandemic which was declared by the World Health Organization (WHO) in March 2020 spread rapidly, affecting millions of people and overwhelming healthcare systems worldwide [1]. With the events of the pandemic, development of effective diagnostic tests, therapeutics, and vaccines to control the spread of the virus and mitigate its impact on public health was necessitated [2].

Medicine regulatory agencies play a crucial role in ensuring the safety, quality, and efficacy of medicines. During the COVID-19 pandemic, regulatory authorities were faced with challenges in adapting their processes and policies to cater for the urgent public health demand for COVID-19-related medical products while maintaining regulatory standards [3].

Regulatory agencies all over the world streamlined and made flexible regulatory processes to tackle the urgent need for COVID-19 medicines[4,5]. Regulatory adaptations included accelerated assessment processes, reliance on data from well-established regulatory authorities, and increased collaboration among stakeholders. Emergency use authorization (EUA) pathways for registration were also established and implemented to expedite the availability of COVID-19 diagnostic tests, therapeutics, and vaccines, making them available for use sooner than they would normally have with traditional regulatory processes [3,6].

Although medicine regulators actively put in efforts to accelerate the availability of COVID-19 medical products, maintaining the safety and efficacy of these interventions cannot be compromised. Monitoring quality and effectiveness of authorized COVID-19 medicines remains the prerogative of regulators through their regulatory oversight and post-market surveillance [7]. Regulators have enhanced their pharmacovigilance activities to detect and respond to adverse events associated with COVID-19 treatments and vaccines [8].
Additionally, the COVID-19 pandemic has prompted regulatory agencies on the importance of global regulatory collaboration and harmonization. International regulatory networks, such as the WHO's Access to COVID-19 Tools Accelerator (ACT-A) and the International Coalition of Medicines Regulatory Authorities (ICMRA), facilitated information sharing, collaboration, and the exchange of best practices among regulators worldwide [9]. Such collaborative efforts aim to ensure alignment in regulatory standards, facilitate data sharing, and streamline regulatory processes to expedite the global response to the pandemic [4].

Method

STUDY DESIGN

The study was conducted through qualitative open-ended interviews to explore the thought pattern of medicine regulation officials on the impact of COVID-19 on medicines regulation in Ghana. The interview guide was developed based on available literature that outlined international adaptations and agility of regulatory agencies during the COVID-19 pandemic.

STUDY SITES

The study was carried out within the head office of the Ghana Food and Drugs Authority; the sole regulator of medicines in the country, hosting various departments for medicine regulation. Respondents were purposively selected from various departments in the organization that played a part in the country's state of emergency with respect to health products and technologies regulation.

SAMPLING TECHNIQUE

Purposive sampling was employed to ensure selection of respondents who could provide information relevant to achieving the objectives of the study. The principle of data saturation was adopted to determine the number of study participants.

DATA COLLECTION, MANAGEMENT AND ANALYSIS

The main tool for data collection for this study was interviews (using an interview guide) conducted either face to face or over the phone depending on the availability and convenience of the respondents. Interviews were audio-recorded with the consent of participants and transcribed for analysis. After transcription data was categorized into themes and analyzed using a generic analysis method. This method involved identifying themes that capture important elements within the data and paying attention to the relationships between themes [10].

Results

OVERVIEW

The COVID-19 pandemic posed significant challenges to healthcare systems worldwide, including the regulation of medicines. In Ghana, as in many other countries, regulators had to adapt swiftly to ensure the availability, quality, and safety of medicines during this crisis. Ghana's medicines regulatory system has been governed by the Food and Drugs Authority (FDA) even prior to the COVID-19 pandemic. The system encompasses pre-market approval, post-market surveillance, pharmacovigilance activities, and approval of clinical trials, aimed at safeguarding public health.

IMPACT OF THE COVID-19 PANDEMIC ON MEDICINES REGULATION

Disruption in the supply chain

The COVID-19 pandemic created disruptions in global supply chains, affecting the availability of essential medicines in Ghana. Regulators were confronted with challenges in ensuring an uninterrupted supply of medicines and medical products as imports and exports had come to a halt following restrictions to limit the rate of spread. This prompted the FDA to implement expedited approval processes for critical COVID-19-related medicines, while also strengthening post-market surveillance and vigilance to monitor quality, safety and efficacy.

Emergency use authorization

To address the urgent need for COVID-19 treatments and vaccines, regulators worldwide, including Ghana, implemented emergency use authorization (EUA) processes. The FDA, in collaboration with international partners, expedited the review and approval of COVID-19 diagnostic tests, therapeutics, and vaccines. This allowed for timely access to potentially life-saving interventions.

Regulators in Ghana recognized the importance of collaboration and information sharing with other national and international agencies, such as the World Health Organization (WHO), and West African Health Organization (WAHO) to ensure alignment with global standards. This collaboration strengthened the capacity of regulators to respond rapidly and effectively to the pandemic.

Regulatory flexibility and adaptability

The FDA demonstrated regulatory flexibility by adopting alternative assessment approaches and streamlining processes without compromising safety and quality standards. This included processing abridged documentation for product registration, leveraging reliance on stringent regulatory authorities for product evaluations and implementing desktop documentation review of manufacturing facilities. Such adaptability enabled timely access to COVID-19 medicines while maintaining regulatory oversight.

The COVID-19 pandemic highlighted the need for increased regulatory capacity and resources in Ghana. The FDA faced resource constraints and workforce limitations, necessitating investments in human capital and technology to enhance regulatory capabilities. Strengthening the regulatory system would not only address immediate pandemic-related challenges but also contribute to long-term preparedness. Harmonizing regulatory standards, processes, and information sharing mechanisms would facilitate a coordinated response to future health crises.

Working Remotely

With employees working remotely, the Authority faced challenges with having a system in place to ensure effective remote work whilst maintaining adequate staffing levels. The absence of employees from physical workspaces led to reduced workforce capacity and limited availability of personnel to carry out essential tasks. Also, considering the new concept of working from home in Ghana, infrastructure required for staff to remotely access work assigned to them was a challenge. This impaired capacity, hindered productivity and placed additional strain on the limited staff physically working in the office.

However, the shift towards virtual training has not only allowed for smarter working practices but has increased the number of staff that can be trained and also substantial cost savings in training of personnel and travelling cost. This innovative approach permitted the submission of applications for emergency use authorization, via electronic platforms, which was easily accessed by assessors. Moreover, the interviewee praised the increased resourcefulness in managing paperwork and the widespread adoption of online training. Notably, the environmental impact of the COVID-19 pandemic was acknowledged, as a responder stated: "We're also saving the environment because we're no longer traveling to work every day and printing too much" (Regulator-1).

Financial constraints

Challenges faced in the industry, particularly regarding financial barriers and capacity issues, were discussed. A respondent emphasized that while the capacity to perform necessary tasks

existed due to staff training provided, the financial aspect posed a significant challenge. The internal revenue generation system of the Food and Drugs Authority relied heavily on internally generated funds from regulatory activities conducted partly on regulated products submitted for registration and reregistration. With the closure of ports during the COVID-19, he questioned: "Where would the things come from and how would you get the percentages to enable the FDA to operate?" (Regulator-2), implying the issues regarding the availability of resources to sustain operations financially. This highlights the necessity to review and revise revenue generation approaches to address similar challenges in the future.

Myths and Misconceptions

The surge of unverified claims regarding medicines for COVID-19 management was another significant issue during the pandemic. Despite the lack of evidence to support these claims, some members of the general public expected the FDA to process such applications. For instance, one company claimed in the media that their product could be used for COVID-19 management without having any substantiating documentation to prove their claim. This led to public belief in such claims, further burdening regulators with the demand to take immediate action.

In response to that, extensive public awareness campaigns utilizing traditional and digital media channels to educate its citizens about COVID-19 were implemented. The Food and Drugs Authority along with other stakeholders and opinion leaders played a crucial role in disseminating accurate information and debunking myths and misconceptions about the pandemic. These efforts aimed to empower citizens with accurate information, dispel misinformation, and promote adherence to preventive measures. The challenge of widespread misconceptions underscores the importance of evidence-based approaches in evaluating and approving treatments during public health emergencies. These included advocacies and press releases to correct some insinuations which were a setback to getting people to accept the interventions to manage COVID-19.

New Guidelines

Prior to the outbreak, the Food and Drugs Authority (FDA) had developed emergency use guidelines in line with the WHO Global Benchmarking Tool maturity level three (3) to enhance their readiness for managing emergencies. Lessons from the Ebola crisis in 2015 led to the development of these guidelines by the FDA that proved valuable in addressing the immediate challenge of the COVID-19 pandemic. "Benchmark audits and the implementation of the emergency use authorization guideline provided a strong foundation for the expedited regulatory process" (Regulator- 3).

To accommodate the unique circumstances, an abridged registration procedure was established to expedite approvals based on minimal submissions. Proactive measures due to the novel nature of the disease, became necessary, leading to modifications and repurposing of existing medicines by the FDA based on international recommendations. A committee was formed to evaluate and update the list of medications based on 1st line, 2nd line and 3rd line treatments for COVID-19 as defined by the national COVID-19 treatment protocol. As new evidence emerged, outdated medicines were removed and replaced with more suitable options. However, the lack of information about the disease posed a significant challenge and hindered the decision-making process.

The FDA collaborated with the Ministry of Health, and the Traditional Medicine Practice Council to develop Efficacy Assessment Guidelines for Herbal Products that was intended for management for COVID-19, ensuring a rigorous evaluation process. These efforts reflect the commitment of regulatory authorities to ensure the safety and efficacy of healthcare products in the face of unprecedented challenges.

The recent completion of a benchmark audit[1112] allowed the FDA to have an Emergency Use Authorization guidance system in place, enabling them to advise the government on necessary actions during the pandemic. "The guidance document actually gave us the blueprint on how we would process everything that came in, the guidance for the legal legislation to be passed, and guidance to the ministry as well", an interviewee said. This indicates that the guidance document played a crucial role in initiating processes, facilitating the declaration of a state of emergency and the passing of legal legislation.

Interventions for COVID-19 Management

The FDA provided guidance on various actions, including measures to improvise the shortage of nose masks, laboratory testing of hand sanitizers, and local production of essential pharmaceuticals. The FDA engaged with the local industry to do a quick assessment of available resources in the country to see how best medication needs could be handled considering most countries were on lockdown. Some pharmaceutical companies had to

redirect their raw material into the production of essentials for the management of COVID-19. An example is the redirecting of alcohol by some local manufacturers into the production of hand sanitizers to augment what was available on the market.

The Authority expedited processing timelines for small-scale producers, facilitating the importation of raw materials for local production of essential pharmaceuticals, supporting the manufacturing of hand sanitizers and expanded their knowledge base to understand the potential use of existing medications for COVID-19 management. Working outside their normal scope, staff of the FDA conducted extensive research on medications initially proposed for COVID-19 management, exploring their potential use and mechanism of action. This collaborative effort and flexibility allowed the FDA to consider products and provide timely recommendations, ensuring effective response measures.

Working together with the Ghana Standards Authority, the FDA developed specifications and standards for the production of nose masks from local fabric, suitable for use and comparable to international standards. This collaboration birthed the publicly available specifications which spelt out to local manufacturers, what was required to make an effective nose mask with regards to fabric, dimensions and design of the nose masks. Hence, the paper-paper-paper layer combination was replaced with calico-calico-calico, calico-paper-calico and calico-stiff-calico combinations that were more effective at reducing the spread of the virus.

Discussion

WORKING REMOTELY

The COVID-19 pandemic disrupted the traditional work environment, requiring organizations to implement quarantine measures. As a result, employees were compelled to work from home, leading to the emergence of various challenges and opportunities. The initial transition from regular office-based desk work to remote work, necessitated by the aggressive spread of the COVID-19 impacted the operations of regulatory organizations negatively. There may have been an immediate situation of chaos and overwhelmed staff due the novelty of the situation and lack of infrastructure to support remote work. Also staff had to adapt to using online tools to produce desired outcomes within the tight timelines and regardless of distractions from daily routines and family distractions[13]. Various studies have highlighted that despite the positive outcomes from remote work adaptations by most organizations some negative implications may have been present. These include increased workload and pressures to produce results which could have contributed to increased stress levels[13].

Remote work necessitated adjustments of staff schedules and working arrangements posing challenges in maintaining adequate human resource capacity. Absence of in-person interactions and the limitations of remote communication tools interferes with prompt addressing regulatory matters [14]. Timely processing of documents is also interrupted with lack of physical presence in the office where these documents may be available. This potentially leads to backlogs and delays in reviewing and approving applications. The staff shortage highlighted the need for proactive measures, such as flexible work arrangements, to ensure the uninterrupted functioning of the regulatory authority. Despite these challenges, the need for uninterrupted functioning of the regulatory authority facilitated the implementation of virtual collaboration platforms and optimizing remote work processes mitigates the burden of reduced staff strength [15]

General COVID-19 restrictions compelled organizations to implement alternative measure to ensure continuity of processes. Virtual meetings had to replace in-person training sessions and seminars which could not be completely scraped out because of the significance of constant professional development, information dissemination and stakeholder trainings. Extensive travel arrangement had to be curbed necessitating the inter-institutional and global collaboration. This adaptive approach has allowed for increased flexibility and improved efficiency in regulatory procedures. It has streamlined evaluation processes, ensuring timely feedback and reducing the burden on applicants, thus facilitated the navigation through the complexities of the pandemic.

While this shift posed challenges and resulted in backlogs in meeting Key Performance Indicators (KPIs), it also brought forth several positive outcomes including improvements in collaboration, cost savings, reduced travel, the adoption of virtual training, regulatory changes, and an increased emphasis on resourcefulness. The transition to remote work despite the initial challenge, encouraged the concept of working smart and more efficiently while saving resources. It is worthy of note that the Authority, currently, even post pandemic, runs a hybrid in-person and remote work schedule with its staff leveraging on the adaptations and smart working experience learned

from the circumstances of the COVID-19 pandemic.

INTERVENTIONS FOR COVID-19 MANAGEMENT

COVID-19 presented as a matter of urgency the need for effective treatments. Medication repurposing, utilizing existing medicines for new therapeutic purposes, became the go to for medicine discovery and treatment. Pharmaceutical industries and researchers aimed to expedite the identification of potential treatments for COVID-19 through medication repurposing, leveraging existing safety profiles and known pharmacokinetics, to address the immediate healthcare challenge of the pandemic. The insights gained from medication repurposing efforts during the pandemic stand the chance of shaping future drug discovery strategies and accelerate the development of treatments for emerging infectious diseases.

In a global state of health emergency, repurposing of approved medicines saves time on time-consuming stages of drug discovery and development process, such as safety testing and dosage determination. It eliminates the cost and risk associated with developing new drug molecules. A number of therapeutic options demonstrated promising results in the management of COVID-19. Among them and common in Ghana were the use of dexamethasone, ivermectin and hydroxychloro-quine [16]. The anti-inflammatory drug dexamethasone showed benefit in managing severe respiratory complications while the antiparasitic agent Ivermectin, showed potential antiviral effects [17]. These repurposable candidates were identified after critical screening of drug molecules with potential antiviral activity or drug-target interactions.

Off-label medicines use is the therapeutic utilization of medicines outside its manufacturer authorized product indication. Off-label use of medications through repurposing of existing medication satisfies in the interim medical needs in emergency situations where time is of the essence especially in cases where options are limited or non-existent. Since inappropriate use of medications can occur with the introduction of off-label medicines use, its appropriateness and ultimate benefit must be critically assessed to establish a favorable benefit to risk ratio [18].

EMERGENCY USE AUTHORIZATION

Various pandemic and terrorist attacks affecting public health influenced the institution of the emergency use authorization. Examples are the 2001 anthrax bioterrorist attacks, H1N1, Zika virus, H7N9 virus, MERS-CoV and Ebola virus [19]. These contributed to the need for emergency measures to counteract the attacks on public health and hence the origination of the emergency use authorization in 2004 [19].

A medication indicated for a particular condition may be found to be beneficial in the management of another condition. Also, in drug development researchers may discover another potential use during the explorative phase. An instance is the development of acyclovir, an antiviral agent, by Gertrude Elion and two of his colleagues from the pharmaceutical industry.

Emergency Use Authorization allows for the use of unapproved medicines or medical measures in the diagnosis, treatment, management or preventions of novel disease conditions with adverse outcomes to address public health emergencies when alternatives are insufficient or unavailable [19,20].

As at April 2020, following the inception of the disease in November 2019 and declaration as a pandemic by the World Health Organization in March 2020, no clear approval had been given for any medication for the management of COVID-19. Countries around the world began implementation of Emergency Use Authorization for options that had been recommended for repurposing. These recommendations were not approvals for use of these agents however, only a means to tackle an emergency situation. The lack of evidence had sections of the scientific community and general public unsettled and raising criticism. Interim guidelines were introduced by relevant institutions and research has subsequently sprang up to generate substantiated evidence for or against the varying opinions [21].

During the pandemic, Chloroqine, Hydroxychloro-quine, Azithromycin among others were recommended for use in the treatment of associated symptoms of the disease and slow down its progression. Along the line some of these agents and therapies failed to show significant benefit or created concerns with safety profile and hence had to be revoked. The introduction of these agents coupled with panic among populace led to increased prescriptions from physicians even outside the recommended criteria for use which was also an issue of public health concern [19,22].

MYTHS AND MISCONCEPTIONS

Many myths have existed about health conditions for several years and have impacted societal response and reaction to these conditions in

different ways. The uncertainty of the COVID-19 pandemic was no different and led to stigma, fear, panic and increased risk of infection [23]. These myths were able to have such an impact by influencing the understanding and preventive actions based on the public point of view.

Perpetuation of myths is usually associated with low literacy. Public health professional and by extension medicines regulators found themselves not just battling a disease state but also the spread of false information on COVID-19. Some countries tackled the 'pandemic of misinformation' by limiting access to telecommunications and the internet to prevent citizens from reaching information which was precipitating fear and panic. This situation was dicey since international regulators of public health including the World Health Organization and health agencies under the United Nations also warned against proliferation of myths being a result of limited access to reliable sources of information [24].

Interestingly, there were individuals who believed that the pandemic was just an idea being sold as part of a hidden political, business or marketing agenda. This made the need to provide frontline workers in-depth training on communication in emergency situations and access to facts and evidence based information an essential one [25]. In Ghana, press releases and national address were issued periodically to shed light on the grey areas subject to propagated misconceptions [26].

FINANCIAL CONSTRAINTS

The COVID-19 pandemic imposed significant financial constraints on the medicines regulatory authority, stemming from various limitations caused by the global health crisis. The redirection of resources to address the immediate public health needs, such as vaccine procurement and healthcare infrastructure enhancement, strained the financial capacity of regulatory agencies. Budgetary cuts and reallocation of funds resulted in reduced resources for the medicines regulatory authority, hindering their ability to carry out essential activities effectively. The limitations on conducting physical inspections and assessments, as well as delays in product approvals, impacted the revenue generated through regulatory fees and services.

Opportunities

The COVID-19 pandemic prompted significant developments in Ghana's healthcare landscape. The establishment of The National Vaccine Institute aimed to coordinate research for local vaccine production was a key milestone. It is expected to operationalize government's vision of securing the much-needed vaccines through domestic vaccine development and manufacturing in the short, medium and long-term phases [27]. Recognizing the importance of local vaccine production, DEK initiated the construction of a manufacturing facility, starting with fill and finish operations.

Ghana gained global recognition for setting the standard in face mask production during the pandemic. Efforts were made to expedite applications through online reviews. Currently, Ghana relies on imports, particularly from India and Europe, where vaccines are produced in large quantities. However, establishing local manufacturing capabilities is crucial to ensure self-sufficiency and scalability. Strengthening the vaccine manufacturing sector will enable increased production and distribution within the country, offering a promising path forward.

Acknowledging the vaccine-driven nature of COVID-19, the government allocated funding to establish a vaccine manufacturing company in Ghana, enhancing the country's future readiness. This move aims to reduce reliance on imported bulk supplies and strengthen the local manufacturing sector, facilitating efficient vaccine distribution.

Conclusion

The pandemic highlighted the importance of resourcefulness and the adoption of sustainable practices, working smarter, saving resources, embracing virtual trainings, and introducing dynamic assessment practices have reshaped the way we work and collaborate. As we continue to navigate the post-pandemic world, these lessons can serve as valuable guides in building a more efficient, collaborative, and environmentally conscious future.

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