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Review Article

Regulatory response to pandemics in a developing country- the case of COVID-19 and the Ghana food and drugs authority (Ghana FDA)

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Abstract

The emergence of the novel coronavirus (COVID-19) has demonstrated the challenge of a single infection to health systems across the globe. The World Health Organization (WHO) declared COVID-19 as a pandemic on 11th March 2020, pointing at the time to the over 118,000 cases of the coronavirus illness in over 110 countries around the world and the sustained risk of further global spread. Congruent to this declaration by the WHO, countries were expected to accelerate their individual efforts amidst striking the right balance between protecting health and preventing economic or social disruption. In response to the pandemic, regulatory authorities of food and drugs in various countries are also recognizing the new demands and obligations that the pandemic has brought and taking measures to meet them and provide the much-needed support. The Ghana Food and Drugs Authority (FDA) has taken various accelerated actions to meet the local demands in managing COVID-19. The regulatory interventions not only aim to facilitate the authorization of medicines and health technologies, sensitize the public on disease prevention and ensure the uninterrupted availability of medical and food supplies but also seek to inspire and boost local industrial potential. The Ghana FDA's efforts are multifaceted and include propping the Drug Supply Chain, expeditious testing of essential COVID-19 medicines, facilitating efforts at COVID-19 test kit evaluation, active post market surveillance and public sensitization on preventive measures. The outcomes of the FDA response have informed ample opportunities that can be leveraged on now and beyond the pandemic and sensitized the Authority on the need to simulate possible emergencies and be better prepared in future happenings.

Keywords: Coronavirus, COVID-19, Ghana Food and Drugs Authority (FDA), pandemic, medical devices, Test Kits, Personal Protective Equipment (PPE)

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1. Introduction

The Ghana FDA is the National Regulatory Authority mandated by the Public Health Act, 2012 (Act 851) to regulate among others, food, drugs, food supplements, medical devices, household chemical substances as well as clinical trials.(1) The availability of the right quality of soap, hand sanitizers, PPE, medicines and test kits for the management of COVID-19 patients fall under the purview of the Food and Drugs Authority (FDA).

Following the declaration of COVID-19 as a pandemic, the FDA has implemented various regulatory measures as part of the national efforts in combating the viral pandemic.

2. Drug supply chain regulation

Hitherto the declaration of COVID-19 as a public health emergency in Ghana, the FDA adopted various measures as part of her preparedness for the pandemic.

A guide was developed on timelines and the documentation needed for expedited registration of medicines needed to fight the pandemic. (2)

Stakeholders within the local pharmaceutical industry were engaged to discuss the importation and manufacture of emergency medicines that will be needed for the fight against the pandemic. Following this engagement, an inventory of available in-country stocks of essential medicines that will be needed during the period of the pandemic was collated so as to project and avert possible shortage of essential medicines. (3)

Local manufacturers and importers were informed of the necessary documentation that will be required to

expedite the registration process for medicines needed to fight the pandemic based on risk.

Following the national declaration of COVID-19 as a public health emergency, the FDA has activated its Guidelines for Emergency Use of Medical Products. This empowers the FDA to permit the application of an unregistered medical product in an emergency situation to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents, when there are no adequate, approved, and available alternatives.

As part of the national fight against COVID-19, the following activities were initiated to mitigate the local spread and treat the existing infections of COVID-19.

Registration and importation of Hydroxychloroquine sulphate Tablets (Plaquenil) and Azithromycin were expedited. This action was in line with the products listed for emergency use in the treatment of Covid-19 as per the Standard Treatment Guidelines for COVID-19 management in Ghana. (4)

Manufacturing permits were equally processed for the local manufacture of Chloroquine and Hydroxychloroquine tablets.

To avoid shortages of medicines and medical products on the market and to minimize face-to-face contact with clients, provision was made for the online submission of renewal and variation applications. (5)

3. Test kits & COVID-19 related Medical Devices

Due to the current upsurge in COVID-19 infections in Ghana and the increased need to expand the testing capability of the country, (6) the FDA Ghana has developed and implemented guidelines for the authorization of emergency use Antigen/Antibody Rapid Diagnostic Test Kits for Sars-Cov-2 Virus. (7) The Medical Devices Department of the Ghana FDA has presently expedited registration of Personal Protective Equipment (PPE) and all COVID-19 related medical devices.

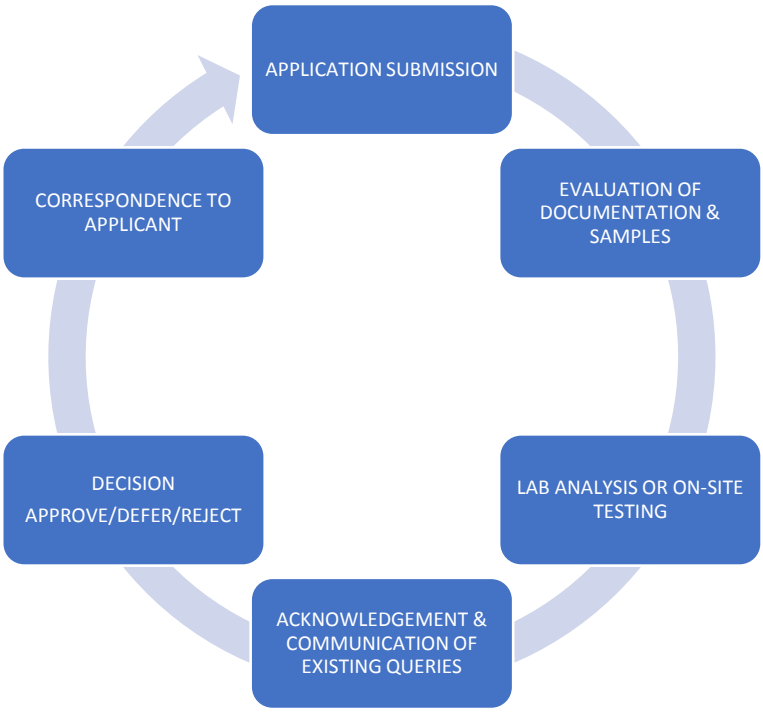

Figure 1. Registration Procedure for Medical Devices

Locally-Manufactured Personal Protective Equipment (PPEs)

Part of the FDA's mandate is to ensure the availability of safe, quality, good performing and efficacious medical products and equipment. In the light of the current global shortage of the supply of PPEs, the Government of Ghana has called on the local Pharmaceutical Industry to increase the local manufacturing of PPEs and medical equipment required for the fight against the COVID-19 pandemic.(8) As part of its contribution to achieve this goal, the FDA with the support of the Ghana Standards Authority (GSA) is facilitating all processes leading to the registration and approval of these PPEs and also making available standards that can be used for the approval of same in the absence of known international standards.(9)

One such product is face masks. The locally-manufactured face masks would be made from textiles. In the absence of the surgical masks (produced from non-woven materials) and respirators, these masks produced from textiles can be used to slow down the spread of the virus. The FDA has subsequently made available a standard that can be used to benchmark the registration of these masks.(10) It is necessary to have this set of standards to ensure that the benefits to be derived from their usage are not eroded by the use of textiles that would be of little or no value.

Another product is Ventilators. Due to global shortage resulting from the COVID-19 pandemic, the FDA has noted the desire of the local industry in partnership with some developers to produce ventilators. In respond to the need, the FDA has made available a set

of requirements that can be used to evaluate these ventilators produced locally.

Figure 2. Locally Manufactured PPE

Figure 3. Local Face Mask

Testing of essential medicines and medical supplies

As part of the Ministry of Health Coronavirus Emergency preparedness and Response in combating the COVID-19 virus, the FDA laboratories are working around the clock to ensure essential medicines and medical supplies that are locally produced, donated or imported towards the mitigation of COVID 19 are expeditiously tested within 24 hours to guarantee conformance with set standards.

The FDA quality control laboratory has further expanded its services and contributed to resource availability by producing alcohol-based hand sanitizers that are used in all the FDA offices nationwide. Under the superintendence of the FDA labs, the Local Government Ministry produced 15,000 bottles of hand sanitizers for onward distribution to the needy in the society.

4. Market surveillance & safety monitoring

The state of emergency created by the pandemic has led to an increased demand in all products related to the alleviation of COVID-19 and thus created the opportunity for unscrupulous individuals to infiltrate the market with substandard products. Thus, the FDA has increased its market surveillance activities to ensure that all such products on the market meet the quality standards and are thus fit for its intended purpose and registered accordingly.

Again, as a result of the novel nature of COVID-19 and the corresponding data deficit on the recommended medicines, the FDA has developed a safety monitoring plan to outline procedures for an enhanced pharmacovigilance system. (11) The enhanced pharmacovigilance system is critical in enabling prompt identification of safety concerns during this pandemic and the adoption of the appropriate risk minimization measures geared at the continual safe and effective use of these medicines. Presently, the FDA is working with the Heads or the Institutional Contact Persons of the COVID-19 Treatment Centers and reports weekly on the incidence of adverse drug reactions.

5. Public sensitization & education

Pursuant to provisions of part seven of the Public Health Act, 2012 (Act 851) which mandates the Food and Drugs Authority (FDA) to promote public health and safety, (1) the FDA is actively involved in a myriad of public sensitization activities.

Public education at market places on COVID-19 awareness and prevention has presently been intensified. Engagements with the media on the preventive measures against the spread of the disease have also heightened.

The FDA presently issues public alerts through its social media handles and website on the need for regular hand washing, the use of hand sanitizers and other protective products for the prevention of the COVID-19 virus.

The use of mobile vehicles has been adopted in community education. Pre-recorded messages in English and local Ghanaian languages are played within these vehicles.

A list of FDA-approved essential medical supplies such as hand sanitizers and face masks has been published to aid consumers in purchasing safe and effective supplies.

Also, the FDA has developed and released various guidelines for restaurants, 'chop bars', food vendors and other eateries. The guidance is aimed at intensifying general hygiene rules, social distancing measures and food safety.

6. Challenges & opportunities

More than ever, the FDA Ghana is faced with various challenges that impact the smooth operations such as the lack of financial and capital resources. The low staff strength borne out of the need for social distancing and the restrictions on movement have further burdened the institutional performance. However, despite the presenting challenges, the FDA has equally identified opportunities including but not limited to the following;

Innovation within local industry: The local industry has proved itself capable in contributing to the country's self-reliance. About 80% of hand-sanitizer retail applications processed by the FDA were of local origin.

The development and implementation of new departmental guidelines has reinforced the institutional strength of the FDA. The chaos of the ongoing pandemic has sensitized the Authority on the need to simulate possible emergencies and be better prepared in future occurrences.

Presently, the pandemic situation has created a platform to debunk/correct some perceived negative opinions of the FDA (e.g. hitherto, some individuals believed FDA frustrated local businesses). Having been faced more than ever with the need for standardized, safe and efficacious medicines and medical products; the public better appreciates and understands the need for FDA approval prior to product availability on the market.

The need for self-reliance in the face of the global pandemic also promoted inter-institutional innovation within governmental agencies and the private industry. Noteworthy is the local production of face masks and ventilators spearheaded by the FDA and GSA.

7. Conclusion

The regulatory adaptations by the Ghana FDA to COVID-19 have resulted in a more robust health system. The resulting framework is better positioned to withstand the present pandemic and future shocks on health security. The FDA has not only developed out of the current crisis but has witnessed a new wave of innovation within the local industry. This new wave aligns adequately with the national goal of self-reliance.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

List of abbreviations

WHO- World Health Organization
FDA- Food and Drugs Authority
GSA- Ghana Standards Authority
PPE -Personal Protective Equipment

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