Jackson, Etti & Edu

COVID-19: DEVELOPMENTS IN THE HEALTH AND PHARMACEUTICAL SECTOR

COVID-19 Newsletter from Jackson, Etti and Edu

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The COVID-19 pandemic continues to adversely affect the world and global economy particularly the health sector. All over the world, nations are beginning to strengthen their health sector in a bid to protect their populace, curb the spread of the coronavirus as well as establish strong and formidable health industries to deal with current and future health hazards.

In this regard, Nigeria is not lagging behind. The country has set in motion policies, measures and interventions required to develop its health sector. In the word of the current Governor of the Central Bank of Nigeria, Godwin I. Emefiele CON, "…We must look inwards as a nation and guarantee food security, high quality and affordable healthcare, and cutting-edge education for our people. For a country of over 200 million people and projected to be about 450 million in a few decades, we can no longer ignore repeated warnings about the dangers that lie ahead if we do not begin to depend largely on what we produce locally. The security and wellbeing of our nation is contingent on building a well-diversified and inclusive productive economy…"

This newsletter appreciates the interventions provided by the Federal Government of Nigeria in a bid to strengthen the health industry of the country. We shall consider below the measures put in place by health-related ministries, departments and agencies of the Government and the opportunities available for businesses in the health and pharmaceutical sector.

A. The Central Bank of Nigeria's ₦100 Billion Health Industry Intervention Fund

The Central Bank of Nigeria ("CBN") has announced a ₦100 Billion credit support intervention fund for the Health and Pharmaceutical Industry in Nigeria. This Fund was created by the apex Bank to bridge the financial and infrastructural gap in the industry as well as improve the technical capacity of the industry to meet the increase in demand for healthcare services in the country. The CBN will be providing this targeted intervention as structured loans or facilities to pharmaceutical companies, manufacturers, health logistics and distribution companies as well as hospitals and healthcare practitioners, who intend to expand their drug manufacturing plant capacities in Nigeria and upscale the provision of health services in Nigeria accordingly.

B. Nigerian Customs Service to Implement Waiver of Import Duty and Fastrack Clearance Procedures

As part of a coordinated response to the Covid-19 pandemic, the Federal Government has approved a waiver of duty for the importation and clearance of all medical equipment and supplies imported into the country. The Nigeria Customs Service has been directed to implement the directive on import duty waiver immediately as a measure to strengthen the medical services and the health and pharmaceutical industries directly as the country continues to combat the spread and treatment of Covid-19 patients across the country.

Likewise, the Nigeria Customs Service has been directed to implement a fast-tracked clearance of all medical consignments and pharmaceutical

equipment or supplies at all ports of entry in the country. This is to ensure the quick clearance and distribution of these necessities to address the pandemic.

C. The Nigerian Investment Promotion Commission (NIPC) Grants Tax Holidays to Investments in Health & Pharmaceutical Sector

The NIPC has announced tax holidays for companies investing in the health and pharmaceutical industry. This measure was announced to stimulate investments in the sector and to ensure that Nigeria develops the much-needed capacity to address the outbreak and minimize the possible impact of the Covid-19 pandemic. The NIPC confirmed that several activities in these sectors will qualify for a three – five years Company Income Tax (CIT) holiday that will be administered under the Pioneer Status Incentive (PSI) Scheme. In essence, investors in designated industry activities and products within the sector will be exempted from payment of corporate income tax for an initial period of three years, with an option of extension for one or two additional years.

Relevant activities that qualify for the Company Income Tax holiday include:

1. **Manufacture of pharmaceuticals and medical chemicals including:**
    - Medicinal active substances to be used for their pharmacological properties in the manufacture of medicaments: antibiotics, basic vitamins, salicylic and o-acetylsalicylic acids.
    - Medicaments such as antisera and other blood functions, vaccines
    - Processing of blood
    - Medical diagnostic preparations
    - Radioactive in-vivo diagnostic substances
    - Biotech pharmaceuticals
    - Medical impregnated wadding, gauze, bandages, dressing.
2. **Manufacture of irradiation, electromedical and electrotherapeutic equipment including**
    - Irradiation apparatus and tubes
    - CT Scanners
    - PET scanners
    - Magnetic resonance imaging (MRI) equipment
    - Medical ultrasound equipment
    - Electrocardiographs
    - Electromedical endoscopic equipment
    - Medical laser equipment
    - Pacemakers
    - Hearing aids.
3. **Manufacture of medical and dental equipment and supplies including:**
    - Surgical drapes and sterile string and tissue; Surgical Instruments including disposables
    - Dental fillings and cements, dental wax and other dental plaster preparations
    - Bone reconstruction cements; dental laboratory furnaces
    - Laboratory ultrasonic cleaning machinery
    - Laboratory sterilizers
    - Distilling apparatus, centrifuges
    - Medical, surgical, dental or veterinary furniture (operating tables, examining tables, hospital beds, dentists chair)
    - Bone plates and screws, syringes, needles, catheters, cannula
    - Dental instruments.
    - Orthopedic and prosthetic devices; medical thermometers.
4. **Construction and operation of non-residential buildings that offer health support including:**
    - Specialized hospitals
    - Diagnostics
    - Laboratories
    - Medical cities

It is expected that these measures will promote and stimulate private sector investment in the health and pharmaceutical sector and bridge the much needed infrastructural deficit in the industry while creating local jobs and ensuring that the benefits of these investments are felt within the economy at large.

D. The National Agency for Food and Drug Administration and Control ('NAFDAC')

In a bid to ensure the production, circulation and use of health/medical equipment and pharmaceutical products necessary to respond to Covid-19 patients and to curb the spread of the viral disease, the NAFDAC has announced regulatory actions and responses. The responses are outlined below:

Product Registration

1. Applications for the registration of products deemed to have urgent public health impact will be processed and given conditional and limited approvals.
2. Products (already being processed for registration) necessary and critical to treat/curb Covid-19 will be expedited and given emergency approvals.

Manufacture of Chloroquine

It is worthy of note that NAFDAC on the 30th of March 2020 released an order approving the manufacture of Chloroquine for Emergency Stock for Possible Clinical Trial Treatment of Covid-19. NAFDAC has advised the general public to desist from the use of Chloroquine without the guidance of a medical doctor or clinician for cases of clinical trial treatment of COVID-19, as It has side effects such as gastrointestinal upset, blurred vision, headache and pruritis (itching). However, the itching can be relieved by using antihistamine. Prolonged use can also cause retinopathy or vision impairment.

Conditional Emergency Use Approval of Medical Devices

Due to the numerous requests for Emergency Use Authorization for diagnostic test kits to support the national response and ensure expanded testing capabilities for Covid-19, the NAFDAC granted the conditional emergency use approval of antibody test kits (IgG/IgM) and antigen tests kits to be used as diagnostics to support public health infrastructure and guide the response necessary to combat and address the pandemic.

The conditional approval is to be subject to the following:

1. Prior registration and approval by reference regulatory authorities such as those of Japan, USA, Germany, Canada, European Medicine Agency, etc.
2. Registration by the Regulatory Authority in the Country of Manufacture
3. Declaration of Conformity
4. Validation/performance evaluation /Clinical Evaluation Report

In addition to these requirements, the full approval of any diagnostic/test kit by NAFDAC for COVID-19 will be subject to in-country validation to assess the sensitivity or rate of failure (i.e., indication of false positives), and specificity.

NAFDAC has stated that a failure by any health personnel or organisation to comply with the requirement may lead to revocation of any approval granted for importation of the products and forfeiture of same to the agency for destruction.

NAFDAC has reduced the "registration to approval" time from 120 working days to 10 working days due to the COVID-19 pandemic.

Clinical Trials ('CTs')

The NAFDAC has directed parties involved in CTs as follows:

1. The need to initiate new trials or include new trial participants in an ongoing trial should be critically assessed by sponsors.
2. Sponsors/investigators may consider using risk assessment to evaluate changes they may want to apply to ongoing trials during COVID-19. For instance:
    a. A temporary halt of the trial at some or all trial sites.
    b. Suspension or slowing down of recruitment of new trial participants.
    c. Site closure.

    Whatever the decision may be, the safety and well-being of patients already participating is paramount and must not be compromised, likewise data validity.

3. Priority will be given to any (new) clinical trial applications for the treatment or prevention of COVID-19 infection, and/or substantial amendment applications to existing clinical trials necessary as a result of COVID-19.

4. Changes to informed consent or new collection by Sponsors during this critical time, will warrant alternative procedures to obtain informed consent legally bearing in mind such subjects may be in quarantine. In case of emergency situations, where trial participants are incapable of giving informed consent (e.g. when under intensive medical care), sponsors shall adhere to the provisions set out in NAFDAC Good Clinical Practice Guidelines, 2016. Visits to the investigator sites for the sole purpose of obtaining re-consent should be avoided, except for reasons related to COVID-19 and alternative ways of obtaining such re-consents should be considered and adequately documented.

5. For changes in the distribution of the Investigational Medicinal Products (IMPs), sponsors must assess the risks relating to the product and consider any alternative shipping and storage arrangements to ensure the IMP and other medications categorized as non-IMPs are provided the participants without compromising the treatment blinding.

6. NAFDAC acknowledges that the COVID-19 situation is likely to introduce more protocol deviations than normal. It is expected that the sponsor escalates and manages such protocol deviations in accordance with their standard procedures and all protocol deviations must be reported to the responsible regulatory bodies (Ethics and NAFDAC).

7. Sponsors/investigators are encouraged to consider the submission of applications for an accelerated assessment when possible.

NAFDAC Operations

It is important to note that Health and Pharmaceutical products and devices (especially products required to cure, eliminate, or curb the spread of Covid-19) are given priority this period. For registration purposes, such products have been classified into two:

1. Products already in the process of registration with NAFDAC: This category of products will be given expedited or emergency approval; and

2. Products that have been not submitted for registration: Manufacturers (or the local representative of manufacturers domiciled outside Nigeria) whose products fall under this category are advised to apply for the registration of such products with NAFDAC, as the Agency as stated that such products will be given limited or conditional approval.

Medical devices required for diagnostics during the Covid-19 pandemic will be given conditional/emergency approval for use, upon the application for same at NAFDAC.

For products that do not fall under the medical or pharmaceutical sector (e.g. food, cosmetics, etc.), NAFDAC will continue with the online registration of such products only. Hence, the registration of such products may be altered, when documents and samples need to be physically submitted at NAFDAC or if such products requires GMP inspection prior to registration.

CLOSING THOUGHTS

While these developments will impact on business decisions and operational procedures within the health and pharmaceutical industry, there will be new regulatory compliance requirements and obligations which companies and business leaders within the industry will have to consider and comply with. These considerations will range from accessing capital or other forms of financing to diversifying products or services to benefit from the Government's intervention or tax incentives. Stakeholders will be required to re-evaluate their business objectives and product lines to ensure that they key into these opportunities and play their part in the overall industry response to the Covid-19 outbreak.

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