



Luxembourg, 06 September 2022

Environmental and Social Data Sheet

Overview

Project Name:	ESSENTIAL API - NIGERIA
Project Number:	20220023
Country:	NIGERIA
Project Description:	The operation aims at increasing the manufacturing capacity of Active Pharmaceutical Ingredients (APIs) in Africa. An allocation of up to USD 12m from the COVID-19 ESSENTIAL API MANUFACTURING IN AFRICA (2020-0584) Global Authorisation is provided to a local manufacturer in Nigeria, supporting the expansion of its facilities to produce several different APIs, which will be used in treatments against malaria.
EIA required:	yes
Project included in Carbon Footprint Exercise ¹ :	no

Environmental and Social Assessment

Environmental Assessment

The Borrower and Promoter of the Project is Emzor Pharmaceutical Industries Ltd., a private company established in Nigeria, dedicated to the manufacturing and commercialisation of pharmaceutical products. The Project financed by the EIB will encompass the construction of a manufacturing plant for the production of Active Pharmaceuticals Ingredients (APIs), as well as the facilities associated to support activities, such as support functions, utilities and related Effluent Treatment Plant (ETP). The Project will be located within the premises of the overall existing campus of the Promoter in Sagamu, Ogun State, Nigeria.

An EIA was already carried out for the overall Emzor pharmaceutical manufacturing site in Sagamu in 2012, with the approval of the competent authority being granted in 2014. The Promoter has therefore undertaken an abbreviated Environmental and Social Impact Assessment (ESIA), in line with the national legislation and EIB Environmental and Social Standards. The abbreviated ESIA for the EIB Project, an addendum to the 2012 EIA report, has been submitted in June 2022. In addition to covering the new API plant and ETP, this abbreviated/addendum ESIA seeks to address any gaps in compliance with the requirement of the 2014 permit. It identifies and assesses environmental and social impacts of the Project, including:

- environmental impacts: dust, noise, traffic disruption, vegetation clearance and biodiversity, ecosystem protection and impacts, waste management and discharge, hazardous materials, etc.;

¹ Only projects that meet the scope of the Carbon Footprint Exercise, as defined in the EIB Carbon Footprint Methodologies, are included, provided estimated emissions exceed the methodology thresholds: 20,000 tonnes CO₂e/year absolute (gross) or 20,000 tonnes CO₂e/year relative (net) – both increases and savings.



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- social impacts: occupational health and safety risks, labour and working conditions, community issues such as impacts on livelihood, stakeholder engagement, etc.

An Environmental and Social Management Plan (ESMP) was prepared as part of the 2012 EIA for the Emzor site, and it has also been updated to include additional mitigation measures identified in the abbreviated ESIA.

The Project has been assessed for Paris alignment and it is considered to be aligned with the low carbon framework of the Climate Bank Roadmap.

Social Assessment

The land acquisition for the overall Emzor site (including all 10ha of land necessary for the EIB Project) had already taken place in 2011-2015, in line with national requirements and the Rehabilitation and Resettlement Plan developed as part of the 2012 EIA. A Memorandum of Understanding (MoU) with local communities and a Community Development Plan, which are requirements under the 2014 permit, are foreseen as part of the abbreviated ESIA. The Community Development Plan will, amongst other things, document the community development measures that Emzor have already been implementing.

Occupational and community health, safety and security, as well as labour management measures, will be implemented in line with overall site ESMP, Emzor OHS and Employment Policies and Code of Conduct in the case of contractors and other third parties.

Public Consultation and Stakeholder Engagement

The 2012 EIA was subject to extensive public consultation. A stakeholder engagement framework and grievance management measures have been developed for the Project, as part of the abbreviated ESIA.

The Promoter will have to ensure compliance with national and EIB Environmental and Social standards and facilitate the access by the public to environmentally and social relevant information, in accordance with the Bank's requirements.

Other Environmental and Social Aspects

The Project makes a significant contribution to the realisation of the UN Sustainable Development Goals (SDGs), notably SDG 3 - Ensure healthy lives and promote wellbeing for all at all ages. It also has an important impact on other SDGs, in particular:

- SDG 1 - No poverty (considering the project takes place in a lower- and middle-income country)
- SDG 9 - Infrastructure and industrialisation (the project will support and increase the manufacturing capacity of pharmaceuticals in Africa)
- SDG 10 - Reducing inequality within and among countries (the project will reduce African dependency on import of APIs)
- SDG 12 - Responsible consumption (as the project will focus on the production of chemicals to be used in the pharmaceutical sector)
- SDG 17 - Partnerships for the goals (as the Promoter will dedicate own resources to the project)

The project will also contribute to SDG 5 - Empowered women and girls and will serve to address specific needs of women, considering the broader economic effect of increased access to healthcare and pharmaceutical products in Sub-Saharan Africa, and the expected outputs of



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the Project. Namely, two of the four APIs to be produced by the Project are expected to be used in combination for the Intermittent Prevention Treatment of malaria in pregnancy.

Regarding the Promoter's capacity, the Promoter will leverage on the experience obtained in the construction and operation of the pharmaceutical facility already existing and located at the same site in Sagamu, where the new plant for the production of API is expected to be created.

Conclusions and Recommendations

The Project addresses the need in the provision of critical medicines to LMICs, in particular in the fight against malaria, a deadly infectious disease. Moreover, it supports the expansion of the pharmaceutical manufacturing capacity in Nigeria and in West Africa, thus having a spill-over effect of knowledge transfer, and a potential for nurturing and retaining talents and skills in the region, as well as enhance the capabilities of the local authorities and pharmaceutical regulatory environment.

The Bank has reviewed the environmental and social capacity of the Promoter, including its organisation and processes, and deemed them to be adequate. The following conditions will apply:

- signed MoU with host communities;
- the updated environmental permit and final abbreviated ESIA report and updated ESMP, as approved by the competent authority;
- the Community Development Plan.

Undertakings

- The Promoter undertakes to comply with cGMP practices for the manufacturing of APIs and pharmaceutical products, and it is requested to ensure all relevant permits and authorisation for conducting the business are updated and valid throughout the implementation of the Project;
- the Promoter undertakes to store and keep updated for 5 years after completion any document as may be relevant for the Project supporting the compliance with the provisions under the Bank's environmental and social standards and shall upon request promptly deliver such document to the Bank.

Considering the above, the project is acceptable for EIB financing from an environmental and social point of view.