

Environmental and Social Data Sheet

Overview

Project Name: PHARMACEUTICAL RDI & INVESTMENTS
 Project Number: 2020-0266
 Country: Spain
 Project Description: Financing of the promoter's pharmaceutical RDI and expansion investments in Spain.

EIA required: no

Project included in Carbon Footprint Exercise¹: no

(details for projects included are provided in section: "EIB Carbon Footprint Exercise")

Environmental and Social Assessment

Environmental Assessment

The project involves investments in i) R&D activities; ii) R&D laboratory equipment; iii) acquisition of new machines to increase manufacturing capacity in the promoter's manufacturing site in San Agustín del Guadalix, near Madrid, iv) installation of solar panels on the above manufacturing site and v) relevant IT solutions. The R&D activities are a central part of the promoter's operations will be embedded in the existing organisational and management structure. The Capex investments will take place in the already authorised existing facilities. Concerning iv), the promoter is awaiting a permit for the solar panel installation from the Town Hall of San Agustín del Guadalix. The project activities are not listed in any annexes of the Directive 2014/52/EU amending the EIA Directive 2011/92/EU and will be carried out in existing facilities already authorised that will not change their scope due to the project.

Other Environmental and Social Aspects

The promoter is conducting its business in compliance with all applicable environmental laws and regulations.

The promoter complies with the following frameworks:

- EU Guidelines on Good Manufacturing Practices (GMP);
- EU Guidelines on Good Distribution Practices (GDP).

In addition, the manufacturing subsidiary of the promoter (SAG Manufacturing) is working towards achieving ISO 14001 Environmental certification in 2021. The promoter is audited, certified and authorised by the Spanish Agency for Medicines and Health Products (AEMPS) as well as other international agencies such as the Brazil National Health Surveillance Agency (ANVISA) for the manufacturing and commercialisation of medicinal products.

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.

The research activities undertaken in the project are aimed to result in improved generic treatments in areas with significant unmet needs (oncology, diabetes, etc.). Therefore, the project is expected to bring positive social impacts.

The 2 500 solar panels will have a peak capacity of 1052 kWp and will be able to cover the plant's total energy consumption during sunlight hours, or almost a quarter of its annual energy consumption. The promoter estimates the CO2 emissions savings to more than 530 tons per year.

Conclusions and Recommendations

The promoter undertakes to inform the Bank without delay of the approval of the installation of the solar panels by the Town Hall of San Agustín del Guadalix.

The project concerns investments in research and development and capex equipment that will be carried out in existing facilities without changing their already authorised scope. This type of activities is not specifically listed in the EIA Directive 2014/52/EU amending Directive 2011/92/EU; therefore, an Environmental Impact Assessment (EIA) is not required. The Promoter has an integrated environmental and quality management system and effective operating procedures in place which are in line with industry standards.

Considering the above, the project is acceptable for Bank financing in environmental and social terms.