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Public

Environmental and Social Data Sheet

Overview

Project Name:	IRBM COVID-19 (IDFF)
Project Number:	20210116
Country:	Italy
Project Description:	IRBM provides a synergistic multifaceted response to tackle coronaviruses. The project supports the development of increased GMP manufacturing, testing and release capacity for the manufacture of COVID-19 vaccines.
EIA required:	no
Project included in Carbon Footprint Exercise[1]:	no

Environmental and Social Assessment

The project concerns investments that are to be made into the furnishing and validation of an existing manufacturing and laboratory facility, together with the associated laboratory and manufacturing equipment. The facility has already been built and is already being utilised for the intended investment purpose. The Promoter has an integrated environmental management policy and effective operating procedures in place which are in line with best industry practice.

The facility falls under the annex II of the EIA directive (2014/52/EU), referring to the manufacture of pharmaceutical products. In line with the applicable national laws, the promoter has obtained all the necessary permits and authorisations from the competent authorities that are required to proceed with the project. The afore-mentioned permits and authorisations have been issued in compliance with Directive 2014/52/EU amending the EIA Directive 2011/92/EU.

The production process of medicinal products has limited environmental impact and the authorised products are subject to environmental risk assessments under directive 2001/83/EC as deemed necessary, in order to complete the relevant marketing authorisation application. The project is located in an area reserved for industrial use with no impact on Natura 2000 sites. The project will be implemented using state-of-the-art technology and will take into consideration environmentally friendly, low energy-and-resource consuming technologies.

Other Environmental and Social Aspects

The promoter is audited, certified and authorised by the relevant Italian authorities for the manufacturing and release of human medicinal products. Furthermore, its quality control laboratory is qualified by the Competent National Authority as well as relevant international

[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.

bodies. The promoter has a robust quality management system and effective operating procedures which have been duly audited by the Competent Authorities and are in-line with ICH and GMP standards. The upgraded facility will comply with the aforementioned standards.

The Promoter is committed to animal welfare and the responsible use of animals for scientific purposes. Moreover, the Promoter complies with the European Directive 2010/63/EU on the protection of animals used for scientific purposes, where applicable.

The project investments tackle coronavirus, including the SARS-CoV-2 virus that causes COVID 19 and it therefore contributes to the EU coordinated response to the COVID 19 crisis. Successful vaccines to combat the disease pandemic reinforce public health sectors and mitigate the socio-economic impact of the disease globally.

The Bank will require that the promoter supplies copies of all the applicable and relevant authorisation documents prior to disbursement.

Conclusions and Recommendations

The project will not result in any significant additional negative environmental and social impacts. It is therefore considered acceptable for the Bank financing in environmental and social terms.