

Environmental and Social Data Sheet

Overview

Project Name:	ANTIVIRAL VACCINE RDI (COVID-19)
Project Number:	2020-0325
Country:	Germany
Project Description:	The promoter is a biopharmaceutical company at the forefront of developing next generation immunotherapies. The project supports the development of a prophylactic vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The investment plan includes R&D expenditures for the development of the product and the design and construction a of large-scale facility for the commercial manufacturing of the vaccine.
EIA required:	no
Project included in Carbon Footprint Exercise ¹ :	no

Environmental and Social Assessment

Environmental Assessment

The project mainly concerns investments in RDI that are expected to be carried out in the Promoter's existing facilities or other research centres already authorised for the same purpose and would therefore not require an Environmental Impact Assessment (EIA) under the Directive 2014/52/EU amending the EIA Directive 2011/92/EU.

Investments are also expected to be made into the furnishing and validation of an existing manufacturing Good Manufacturing Practices (GMP) - certified² facility together with associated laboratory and manufacturing equipment and at a later stage furnishing and validation of a new manufacturing GMP facility to enable for vaccine pandemic supply. BioNTech has an integrated environmental management policy and effective operating procedures in place which are in line with best industry practice.

The GMP facilities fall 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 construction of the new facility. The afore-

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.

² means that the manufacturer has demonstrated a strong regulatory commitment and compliance to international GMP standards.

Luxembourg, 15 May 2020

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 carried out according to state-of-the-art technology and will take into consideration environmentally friendly, low energy-and-resource consuming technologies.

Other Environmental and Social Aspects

BioNTech is audited, certified and authorised by the relevant German authorities for the manufacturing and release of investigational human medicinal products. Furthermore, its quality control laboratory is qualified by the Competent National Authority as well as relevant international 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 cGMP standards. The new facility will comply with the aforementioned standards.

The project supports research related to the virus SARS-CoV-2 that causes COVID 19 and it therefore contributes to the EU coordinated response to the COVID 19 crisis. A successful vaccine to combat the disease pandemic will reinforce public health sectors and mitigate the socio-economic impact of the disease globally.

BioNTech will supply the Bank with copies of all the applicable and relevant authorisation documents during the due-diligence procedure.

Conclusions and Recommendations

The project has the potential to result in significant positive social impacts in absence of additional negative environmental impacts. It is therefore considered acceptable for the Bank financing in environmental and social terms.