



European Investment Bank (EIB)

Luxembourg, 21 December 2023

Environmental and Social Completion Sheet (ESCS)

Overview

Project Name:	COVID-19 VACCINE RDI SPAIN
Project Number:	2021-0440
Country:	Spain
Project Description:	<i>The project supports the company's investments to develop vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).</i>

Summary of Environmental and Social Assessment at Completion

The project covered the promoter's investments in research, development, and innovation activities in the biotechnology sector, enabling the company to research, develop and gain a marketing authorisation for a COVID-19 vaccine.

Investments were also made into the furnishing and validation of an existing manufacturing facility, together with associated laboratory and manufacturing equipment. The facility was furnished to enable vaccine production and final product formulation. 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 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 mentioned permits and authorisations were issued in compliance with Directive 2014/52/EU amending the EIA Directive 2011/92/EU.

The authorised products are subject to satisfactory environmental risk assessments under directive 2001/83/EC as a pre-requisite to gaining marketing authorisation approval. The project was located in an area reserved for industrial use with no impact on Natura 2000 sites. The project was carried out according to state-of-the-art technology taking into consideration environmentally friendly, low energy-and-resource consuming technologies.

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 best-industry practices. The promoter's R&D practices are in compliance with relevant national and EU regulations (directives 2001/83/EC, 2005/28/EC, 2001/20/EC and Good Clinical Practice, as applicable).

The promoter is audited, certified, and authorised by the relevant Spanish 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 bodies.

Summary opinion of Environmental and Social aspects at completion:

EIB is of the opinion based on the above, that the Project has been implemented in line with EIB Environmental and Social Standards, applicable at the time of appraisal.