Luxembourg, 16 May 2019

Public

Environmental and Social Data Sheet

Overview

Project Name:	NEUROSCIENCE R&D AND INVESTMENT PROGRAMME
Project Number:	2018-0136
Country:	Spain
Project Description:	The project concerns the promoter's R&D activities in its strategic therapeutic areas in neuroscience, in particular in neurology, psychiatry and pain management. The project also focuses on gene therapy of rare diseases. In addition, the Bank's financing will support a company-wide digitalisation programme, upgrading of the manufacturing facilities and various investments that will bring about environmental benefits.
EIA required:	no
Project included in Carbon Footprint Exercise[1]:	no

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

Environmental and Social Assessment

Environmental Assessment

The project includes primarily RDI activities for the development of medicinal products as well as digitalisation activities. The Capex investments concern addition and upgrading of manufacturing equipment to be used in the existing facilities. The project components that mitigate climate action are related to the promoter's business line and include measures to increase energy efficiency and better manage waste water. 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 audited, certified and authorised by the relevant Spanish authorities (AEMPS) for the manufacturing and release of human medicinal products. 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.

Furthermore, the promoter's workplaces in Spain, including the R&D headquarters have an ISO 14001-certified environmental management system and their R&D practices comply with relevant national and EU regulations for pharmaceutical R&D activities (directives 2001/83/EC, 2005/28/EC, 2001/20/EC and Good Clinical Practice, as applicable).

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

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The promoter is committed to animal welfare and their responsible use for scientific purposes. Moreover, the promoter complies with the European Directive 2010/63/EU.

Conclusions and Recommendations

The project concerns investments in research and development, digitalisation, manufacturing upgrading and environmental optimisation that will be carried out in existing facilities without changing their already authorised scope. An Environmental Impact Assessment (EIA) is therefore not required under EIA Directive 2014/52/EU amending Directive 2011/92/EU. The promoter has an integrated environmental management policy and effective operating procedures in place, which are in line with best industry standards.

The research activities undertaken in the project aim to result in new and improved medicinal products with a positive impact on healthcare. Therefore, the project, if successful, is expected to bring a positive social impact.

Considering the above, the proposed investments do not require any additional permits and fall within an already authorised scope. As such, the project is acceptable for Bank's financing in environmental and social terms.