

Environmental and Social Data Sheet

Overview

Project Name:	ALFASIGMA INNOVATIVE DRUGS RDI
Project Number:	2018-0628
Country:	Italy
Project Description:	The project concerns the promoter's R&D activities in the time frame 2019 to 2022, related to the development of innovative medicines in the areas of gastroenterology, vascular medicine and rheumatology.
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's R&D activities are a central part of the promoter's operations and will be embedded in the existing organisational and management structure. The project will not result in any residual environmental impact as it will be carried out in existing and authorised research facilities. The operating procedures in place are in-line with best industry standards and are regularly audited externally.

Other Environmental and Social Aspects

The promoter is audited, certified and authorised by the relevant Italian authorities (AIFA) 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 is ISO 18001:2007 certified and their 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 committed to animal welfare and their responsible use for scientific purposes. Moreover, the promoter complies with the European Directive 2010/63/EU.

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 100,000 tons CO₂e/year absolute (gross) or 20,000 tons CO₂e/year relative (net) – both increases and savings.

Luxembourg, 9 April 2019

Conclusions and Recommendations

The project concerns investments in research and development 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 project is acceptable for Bank financing.

PJ/SQM/ECSO 20.02.2019