



Luxembourg, 17 December 2024

Environmental and Social Completion Sheet (ESCS)¹

Overview

Project Name: ALFASIGMA INNOVATIVE DRUGS RDI
 Project Number: 2018-0628
 Country: Italy
 Project Description: The project concerned the promoter's R&D activities in the timeframe 2019 to H1 2024, related to the development of innovative medicines in the area of gastroenterology, vascular medicine and rheumatology.

Summary of Environmental and Social Assessment at Completion

EIB notes the following Environmental and Social performance and key outcomes at Project Completion.

Environmental Assessment

The project's R&D activities are a central part of the promoter's operations and have been embedded in the existing organisational and management structure. The project has not resulted in any residual environmental impact as it has been 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 continues to be 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 45001 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.

Summary opinion of Environmental and Social aspects at completion:

EIB is of the opinion, based on reports from the promoter and site visits by the EIB team at completion, that the Project has been implemented in line with EIB Environmental and Social Standards, applicable at the time of appraisal.

¹ The template is for ILs and FLs