

European Investment Bank (EIB)

Luxembourg, 20 December 2023

Environmental and Social Completion Sheet (ESCS)

Overview

Project Name: ANAESTHETIC DRUG DEVELOPMENT

Project Number: 2018-0783 Country: Germany

Project Description: The Promoter is a pharmaceutical company developing a novel short-acting anaesthetic compound. The eligible investment plan includes R&D and related expenses to finance the development and regulatory filing of the drug, including the costs associated with a paediatric formulation of the product.

Summary of Environmental and Social Assessment at Completion

The project covered the promoter's investments in research, development and innovation activities in the pharmaceutical and biotechnology sectors, enabling the company to bring a novel anaesthetic medicinal product to the market. The project's activities are not listed in any of the annexes of the EU Directive 2014/52/EU amending 2011/92/EU. Furthermore, the project was carried out in existing facilities already authorised for similar activities and volumes. Therefore, an Environmental Impact Assessment (EIA) was not required.

The promoter's R&D practices are in compliance with relevant national and EU regulations (directives 2001/83EC, 2005/28/EC, 2001/20/EC and Good Clinical Practice, as applicable) and the promoter maintains adequate internal procedures and management practices.

The project has been performed according to state-of-the-art technology and has taken into consideration environmentally friendly, low energy-and-resource consuming technologies.

The promoter has a robust quality management system and effective operating procedures which are in-line with best industry practice.

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.