European Investment Bank

Luxembourg, 22 July 2025

Environmental and Social Data Sheet

Overview

Project Name:	FRESENIUS PHARMA & MEDICAL DEVICES RDI PROGRAMME
Project Number:	2024-0761
Country:	Germany, Spain, France, Italy, Netherlands, Poland
Project Description:	The Project relates to the Promoter's expenditures in Research, Development and Innovation in its portfolio of biosimilars, generic drugs, infusion therapies, clinical nutrition products and the devices for administering these products as well as capacity expansion investments in existing facilities.

EIA required: no

Project included in Carbon Footprint Exercise[1]: no

Environmental and Social Assessment

Environmental Assessment

The Project consists of a four years' investment plan (2025-2028) to be implemented by the Promoter through its Operating Company Fresenius Kabi, focused on the development and manufacturing of highly complex biopharmaceuticals, clinical nutrition, medical technologies, and I.V. generic drugs. More specifically, the Project covers two components, namely:

i) Development activities on small molecules (i.e., generics) and biologics products (so-called "biosimilars"), targeting a range of different therapeutic areas. The activities are expected to be carried out by the Promoter across its different already existing research and development sites located in the EU, as well as in collaboration with partners and third parties.

ii) Capacity expansion of the Promoter's manufacturing footprint in the EU for generics, biosimilar products and clinical nutrition consisting of new capex investments in existing facilities.

The Research, Development and Innovation (RDI) activities at point i) above are expected to be carried out in sites in the EU, and they are not subject to an EIA procedure according to Directive 2011/92/EU as amended by Directive 2014/52/EU. The Promoter minimises the use and testing in animal models during its RDI programmes. Moreover, it employs an internal process for Clinical Trial Quality Risk Management, which is governed by the internal Quality Management System (QMS) and ICH GCP E6 guidance on Good Clinical Practices.

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

Luxembourg, 22 July 2025

The biological agents utilized in the Promoter's operations are classified under Biosafety Level 2 (BSL-2). Where appropriate, the Promoter employs single-use technologies and decontamination processes to enhance biosafety measures.

Regarding the capacity expansion activities to be carried out at point ii) although the sector (production of pharmaceutical products) falls under Annex II of Directive 2011/92/EU as amended by Directive 2014/52/EU, the project financing does not fall under point 13 of the above-mentioned Directive, as the investments take place in existing facilities without a significant negative environmental impact.

Therefore, the capacity expansion activities are not subject to an EIA procedure. The promoter utilises an environmental management system and safety programmes and is conducting its business in compliance with all applicable environmental laws and regulations.

It operates using Good Manufacturing Practices (GMPs), and its manufacturing facilities are designed and constructed according to EU and FDA (US Food and Drug Administration) requirements. The company holds a series of certificates Quality Management (ISO 9001, ISO 13485, ISO 13485 MDSAP Certificate, etc.) Environmental Management (ISO 14001) and Energy Management ISO 50001) Occupational Health and Safety Management (ISO 45001).

EIB Paris Alignment for Counterparties (PATH) Framework

The counterparty is in scope and screened out of the PATH framework, because it is not considered high emitting and/or high vulnerability**.**

Other Environmental and Social Aspects

The Promoter has implemented a comprehensive Health and Safety Management System, which includes primary and ongoing personnel training based on detailed written safety protocols. The promoter's facilities are constructed in full compliance with all relevant environmental, health, and safety regulations. Regular inspections of working conditions, such as artificial lighting levels, noise, temperature, humidity, and air velocity, are conducted by an accredited independent laboratory.

In addition, considering the focus of the Promoter on generics and biosimilars (which are traditionally characterised by a lower price-point compared to originators' products), the Project is expected to provide additional added value.

The Project contributes to implement UN Sustainable Development Goals (SDGs), notably SDG 3 – Ensure healthy lives and promote wellbeing for all ages, SDG 8 – Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work.

Conclusions and Recommendations

None of the project components require an EIA process.

The Promoter's strong governance and operational capabilities ensure the successful execution of the project, supported by their robust experience in advanced biopharmaceutical manufacturing processes.

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Luxembourg, 22 July 2025

Overall, the project not only meets EIB's public policy objectives but also delivers substantial economic, social, and environmental benefits. As such, the project is acceptable for financing in environmental and social terms.