



Luxembourg, 16 October 2023

Public

Environmental and Social Data Sheet¹

Overview

Project Name:	ROMANIAN PHARMACEUTICAL R&D PROJECT
Project Number:	20220855
Country:	Romania
Project Description:	The project supports the investments of a Romanian midCap Pharmaceutical Company into development of new productions lines, their digitalisation processes as well as into new R&D capacities.
EIA required:	no
Invest EU sustainability proofing required	yes
Project included in Carbon Footprint Exercise ² :	no

Environmental and Social Assessment

The Promoter is the most important Romanian producer of generic medicines.

The Promoter's investments financed through this operation concern the development of R&D capacities for pharmaceuticals across a large portfolio of therapeutic classes and consist of the establishment of a state-of-the art facility centre (INOVA+) for such purposes.

The project concerns investments in research and development activities carried out by the Promoter and its partners in existing facilities without changing their already authorised scope. The research and development activities of the project do not fall under either Annex I or Annex II of the EIA Directive 2011/92/EU amended by Directive 2014/52/EU.

Furthermore, the project will encompass the financing of capital investments required for the completion of a manufacturing facility compliant to Good Manufacturing Practice (GMP), to expand the Promoter's manufacturing capabilities of the Company's sterile (topical and sterile) products. This includes inter alia the furnishing of the plant with best available manufacturing

¹ The information contained in the document reflects the requirement related to the environmental, social and climate information to be provided to Investment Committee as required by the Invest EU Regulation and it represents the equivalent of the information required in the template of the InvestEU sustainability proofing summary

² 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.



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equipment and technologies, creation of a pilot tech-transfer centre, R&D and quality control laboratories within an existing building.

The Promoter planned the building of a new Warehouse for Finished Product, which is expected to be built as an extension of the Promoter's current building, situated in Iasi, Romania. The Promoter has already received all the relevant permits for the construction of the facility from the Town Hall of Iasi in 2022 as well as from the Romanian The Ministry of Environment, Water and Forests – the Agency for the Environmental Protection Iasi in 2023. The project was screened out for an EIA by the Agency for the Environmental Protection Iasi (Decision Nr 190 from 23.02.2023). The project will be implemented at the Company's headquarters located in Iasi, Romania, a cohesion area of Europe.

The Promoter maintains adequate internal procedures and management practices that are in line with best industry standards and are subjected to audits. The project will be carried out according to state-of-the-art technology and will take into consideration environmentally friendly, low energy- and resource-consuming technologies.

EIB Paris Alignment for Counterparties (PATH) Framework

The Promoter is in scope but screened out of the PATH framework as it does not operate in a high emitting sector and is not considered as a highly vulnerable counterpart.

Climate Assessment

The project has been assessed for Paris alignment and is considered to be aligned both against low carbon and resilience goals against the policies set out in the Climate Bank Roadmap and/or associated guidance and other relevant documents (e.g. the Energy Lending Policy). The project complies with the Directive 2010/31/EU in relation to the energy performance of buildings, and is in line with the Romanian energy efficiency requirements. In 2022, the 100% of the energy consumption came from green sources among which 25% is from an investment into a photovoltaic plant which will also serve the new facilities.

Social Assessment

The project supports a promoter that has consistently promoted gender equality across the organisation, including through the implementation of specific measures aimed at providing inclusive quality employment and growth opportunities for its women employees. As a result, in 2022, women, who represented 55% of the overall workforce, accounted for 50% of the Executive Directors, 60% of top management and 74% of middle management, up from 20%, 50% and 58% respectively in 2017. The project will further contribute to the development of the promoter's women's health portfolio, which aims at providing women of all ages with therapeutic and preventive solutions for common women's health issues and physiological conditions."

The project does not have any significant negative social impacts.

The project is expected to generate positive social benefits by promoting innovation and technological breakthroughs in the development of essential medicinal products, thus offering access to affordable potential treatments for unmet medical needs, and enhancing patients' quality of life. By supporting skills development and upgrading, the project is expected to provide significant socio-economic benefits, helping to create and retain highly skilled jobs. In this way, it will strengthen regional socio-economic prosperity and position in global value chains, enhance growth and competitiveness of a cohesion region in Romania and beyond.



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Other Environmental and Social Aspects

The Company's quality management system complies with the requirements of the ISO 9001:2015 standard, and together with the environmental standards (ISO 14001:2015) and the occupational health and safety standards (ISO 45001: 2018), they form the integrated management system, which contributes to the growth of a high quality product portfolio.

The Promoter is committed to animal welfare and the responsible use of animals for scientific purposes. Moreover, the Promoter complies with the European Directive 2010/63/EU on the protection of animals used for scientific purposes, where applicable

The Promoter ranks 19th in the top 5% of the pharmaceutical sub-industry out of 452 companies worldwide in terms of ESG (Environmental, Social, Governance) performance, a set of non-financial criteria used by investors to assess the environmental, social, and governance performance and impact of companies. The Promoter's ESG score for 2022 can also be accessed on the BVB website.

Conclusions and Recommendations

The Promoter has effective E&S policies and operating procedures in place, which are in line with industry standards.

The project concerns investments in research and development and manufacturing for which no significant impact on the environment is expected.

Sustainability proofing conclusion: the project is carried out in compliance with applicable national and EU environmental and social legislation. Based on the environment, climate and social (ECS) information and based on the review of the likely significant ECS risks and impacts and the mitigation measures and management systems in place, the project is deemed to have low residual ECS risks and impacts. No further sustainability proofing is required.

Considering the above, the project is acceptable for the Bank's financing in environmental and social terms.