European Investment Bank

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Public

Environmental and Social Data Sheet[1]

Overview

Project Name:	NEXT GENERATION AST (IEU TI HERA)
Project Number:	2024-0937
Country:	Poland
Project Description:	The project covers the Promoter's investments into the development of next generation antibiotic susceptibility testing technologies, including - inter alia - product enhancement, IP, regulatory approvals and market access.

EIA required:	no
Invest EU sustainability proofing required	yes
Project included in Carbon Footprint Exercise[2]:	no

Environmental and Social Assessment

Environmental Assessment

The Promoter is a Polish medical technology company that is developing an automated antibiotic susceptibility testing system, with applications for use in hospitals and laboratories to determine the appropriate antibiotic for clinical care.

The project supports investments in research and development activities carried out by the Company 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, therefore an EIA procedure is not required.

Climate Assessment

The project has been assessed for Paris alignment and is considered to be aligned with both low-carbon and resilience goals as per the policies set out in the Climate Bank Roadmap and/or associated guidance and other relevant documents (e.g. the Energy Lending Policy).

[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.

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

Approximately EUR 5 m in capital expenses is planned as part of the project; all is for equipment to be installed in existing facilities (their own R&D facilities and at a contract manufacturer).

Social Assessment

The project concerns RDI related to developing a novel automated antibiotic susceptibility testing system and related panels to enable rapid access to effective antibiotic therapy, improving patient care and potentially saving costs of complications and longer stays due to ineffective therapies. Furthermore, the use of effective antibiotics helps limits the development of resistant bacteria, extending the use of the current arsenal of antibiotics. Through the R&D activities and investments, the Company is also expected to sustain its current level of highly skilled personnel while contributing to European scientific innovation, supporting the vital research community.

The Company and its products are regulated to ensure quality and reliability of its medical products. Their quality management system is in compliance with the relevant quality management system regulations (EN ISO 134585:2016) and the company is seeking compliance of their devices and panels with EU Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (IVDR).

The Promoter's R&D facilities and practices comply with relevant national and EU regulations and the promoter maintains adequate internal procedures and management practices, especially with regard to labour standards and occupational health and safety. The Company's products are entirely ex vivo (used outside the body) diagnostic tests, thus animal and human testing are not part of the development process (e.g. the Company's tests are performed in test tubes).

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 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, the review of the ECS risks and impacts and the 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, taking into consideration the Environmental, Social and Climate impacts of this RDI project, including the capacity of the promoter and the overall net positive social impact, this project is deemed acceptable for the Bank's financing under environmental and social terms.