Luxembourg, 14.06.2017

Environmental and Social Data Sheet

Overview

Project Name:	PARENTERAL SOLUTIONS INDUSTRIAL PROJECT PORTUGAL
Project Number:	2016-0789
Country:	Portugal
Project Description:	The project concerns the investment in a new parenteral unit in order to produce Large Volume Parenteral (LVP) Solutions and Small Volume Parenteral (SVP) Solutions.
EIA required:	yes
Project included in Carbon Footprint Exercise[1]:	no

Environmental and Social Assessment

Environmental Assessment The project concerns the investment in a new manufacturing facility for Large Volume Parenteral (LVP) solutions and Small Volume Parenteral (SVP) solutions for the pharmaceutical industry and falls under Annex II of Directive 2011/92/EU as amended.

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The plant will be built in the industrial park Manuel Ferreira Lourenço in Mortágua, Portugal (situated in a Less developed region). The promoter already has a manufacturing facility on the same site, for the production of semi-solid and liquid dosage forms. The Promoter has an integrated environmental management policy and effective operating procedures in place which are in line with best industry standards.

In line with the applicable national laws, the new production facility requires an EIA which has been approved by the competent authority in December 2016. Natura 2000 areas are not concerned. The production process of medicinal products has limited environmental impact. The project will be carried out according to state-of-the-art technology and will take into consideration environmentally friendly, low-energy-and-resources consuming technologies.

The adjacent existing facility of the promoter on the same site is GMP certified and authorised by the Portuguese National Authority of Medicines and Health Products (INFARMED) for the manufacturing and importation of human medicinal products. Furthermore, its Quality Control laboratory is pre-qualified by the Competent National Authority as well as relevant international bodies. The Promoter has an integrated quality management system and effective operating procedures in place which are in line with industry standards. The new facility will comply with the said standards.

[1] Only projects that meet the scope of the Pilot Exercise, as defined in the EIB draft Carbon Footprint Methodologies, are included, provided estimated emissions exceed the methodology thresholds: above 100,000 tons CO2e/year absolute (gross) or 20,000 tons CO2e/year relative (net) – both increases and savings.

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Other Environmental and Social Aspects

The new facility will produce novel medicinal delivery devices with a number of lower environmental impact advantages in terms of less waste, and lower energy consumption.

Social Assessment

The project primarily have a positive two-fold social impact: First, through significant job-creation in a less-developed region of Portugal suffering from low economic activity and a relatively high unemployment. Secondly, the project is expected to lead to an increasing consumer surplus as this project will increase availability and accessibility of a high-quality lower priced end-product.

Conclusions and Recommendations

The respect of the environmental management plan and any mitigation measures as outlined in the approval of the EIA will form a contractual undertaking.

The project will not result in significant additional negative environmental and social impacts compared to the current situation without the project. It is therefore considered acceptable for the Bank financing.